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14. ABSTRACT This report summarizes progress and achievements for the grant entitled "Targeted ablation of CML stem cells". The work was initiated at the University of Kentucky in April of 2003, and transferred to the University of Rochester in December of 2003. The work was completed at the University of Rochester and encompasses studies using both mouse and human systems.					
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Introduction

The IMITS: Information and Clinical Technologies for the Advancement of Healthcare is focused on implementation of advanced technology solutions that eliminate inefficiencies, increase utilization, and improve quality of care for active duty forces. The work on this project has focused on the development and implementation of prototype telemedicine systems and advanced technology applications at United States Air Force bases. Emphasis has been placed on the development of sound evaluation methodologies for each of the sub-projects with special attention to the areas of cost effectiveness and end-user satisfaction within the AFMS.

Body

Teleradiology

Develop and implement a symmetrical load-balancing distributed radiology workflow infrastructure at Wilford Hall Medical Center (WHMC).

The distributed radiology workflow research project has been submitted as part of the IMITS FY05 Teleradiology Proposal. This proposal was awarded in September 2006.

Provide funding support for Digital Imaging and Communications in Medicine (DICOM) Modality Worklist(DMWL) Services project .

In early 2006 UPMC submitted a purchase order with AGFA for DMWL services. The installation of the AGFA DMWL was postponed for until late 2006 pending the completion of DITSCAP testing and Stentor recertification. Stentor was DITSCAP recertified in mid-October. The PACS Administrators at Wright Patterson Medical Center will be responsible for installation and support of DMWL at the Medical Center.

The following projects were completed at the request of and in support of Wright-Patterson Air Force Base (WPAFB) Medical Center. These tasks were completed in addition to or in place of the original statement of work.

Extended Stentor Maintenance was provided through October, 2006, for Wright-Patterson AFB Medical Center

UPMC purchased extended maintenance for the Stentor system at Wright-Patterson. The maintenance coverage expired in October 2006. A plan was developed to transition the roles and responsibilities for the maintenance of the Stentor system, as well as, UPMC developed systems from UPMC to Wright-Patterson. This plan will be executed in the first quarter of 2007.

Provide a Training and Turn-over Program for the Wright-Patterson Information Systems Group

This SOW was not contained in the original proposal. UPMC will be providing a two-day training/turn-over program/meeting at the Wright Patterson Medical Center in the first quarter of 2007. The topics to be covered include a UPMC custom software and hardware review, management training, and System architecture review and planning.

Teleradiology Stentor Implementation Evaluation Project ***Evaluate the impact of implementation and usage of the prototype Stentor Image and Information Management System at Wright Patterson Medical Center.***

In 2006, UPMC completed all deliverables associated with the FY 02/04 Teleradiology Stentor Implementation Evaluation Project. A comprehensive final evaluation report, ***IMITS Teleradiology Project Stentor Implementation Research Study Final Evaluation Report***, was prepared and delivered to the USAF SGR in November, 2006. The report was also submitted to the University of Pittsburgh IRB, Wright-Patterson IRB, and the Army HSRRB. This final report submission to the IRBs and the HSRRB officially closed the research activities associated with the FY 02/04 Teleradiology Stentor Implementation Project.

Research focused on user satisfaction, system functionality, and changes in timeliness, work efficiency, and patient care. The study consisted of surveys, interviews, site visits, and diagnostic imaging statistics.

Reportable Outcomes

Presentations

- Chang, PJ; Ruck, WR; Anthony, L; Roberts, JA; and Friedman, C. (2004). *Effectiveness of a Cooperative Load-Balancing Teleradiology Workflow Model*. Oral Presentation. 2004 American Telemedicine Association Conference. Tampa, FL.
- Roberts, JA; and Anthony, L. (2004). *Teleradiology Project Flyer*. Developed for 2004 American Telemedicine Association Conference. Tampa, FL.
- Anthony, L. (2004). *IMITS Evaluation Studies*. Presentation at IMITS FY 04 Project Kickoff Event. Pittsburgh, PA.
- Anthony, L; Roberts, JA; Quenneville, DJ; Gadd, C; and Krills, S. (2005). *Can a Sophisticated Teleradiology Workflow Model Maximize Military Radiology Services?* Oral Presentation. 2005 American Telemedicine Association Conference. Denver, CO.
- Roberts, JA; and Anthony, L. (2004). *Teleradiology Project Flyer*. Developed for 2005 American Telemedicine Association Conference. Denver, CO.

Conclusions

The evaluation project was successfully implemented and the results are encouraging. The primary goal of this project was to evaluate the impact of deployment of the prototype Stentor system at Wright-Patterson Medical Center. It was hypothesized that the Stentor system could be implemented within existing workflows and might be useful in providing more timely diagnoses and consultations.

The evaluation component of the Teleradiology Project (Stentor Implementation Study) was approved by the University of Pittsburgh IRB, Wright-Patterson Air Force Base IRB, and the Army's HSRRB. The exempt approval process was obtained in four months. Because each governing institution based approval of studies on the same federal regulations, efforts were made to streamline IRB approval processes. Each agency, however, continued to require full submission in compliance with their processes. The time required to gain full approval to conduct research can be a barrier for UPMC contracted agencies conducting research in Air Force settings.

Implementation of the Stentor System was significantly delayed based on the requirements of the DITSCAP approval process. The approval process took over a year to complete. This time consuming certification process may have curbed user enthusiasm for this new technology. DITSCAP certification was, however, noted as one of the project's greatest accomplishments.

Results from surveys and interviews were summarized and reported to UPMC project management. Throughout the course of the Teleradiology Project, this feedback contributed to project development decisions and alerted project managers of issues that needed monitoring or immediate resolution.

UPMC and the Air Force have benefited from the trials and tribulations of this project. Lessons learned will benefit the upcoming FY 05 Teleradiology Project, which focuses on workload distribution across multiple Air Force Medical Centers. Evaluation activities will continue to supplement project development.

Teleaudiology

Conduct Feasibility Study to evaluate remote access, monitor, and adjust cochlear implants.

Individuals from Wilford Hall Medical Center (WHMC) and UPMC continued to participate in the project team based on their expertise in Audiology throughout 2006. The project team continued to investigate a remote mapping solution with the three cochlear implant manufacturers within the United States. The manufacturers are Cochlear Americas, Advanced Bionics, and Med-El. All three manufacturers are continuing to participate on the project; however they had very limited resources to dedicate to the project during 2006. A detailed evaluation, by the project team, was conducted to document the current requirements and procedures with regard to cochlear implant mapping. In addition to the current requirements and procedures, the project team documented the requirements and procedures for the proposed remote mapping process. These processes are outlined in Appendix A. A needs assessment and a gap analysis, based on these observations, will be provided to the office of the Surgeon General of the US Air Force in 2007.

The project team and the manufacturers were able to demo the proposed solution for remote cochlear implant mapping in March 2006 at WHMC. Remote cochlear implant mapping will use video conferencing equipment (VTC) and remote control software. WHMC has selected the Polycom Mobile Responder for their VTC equipment and DameWare as the remote control software. UPMC has selected the Polycom MediCart for their VTC equipment and will choose either DameWare or Windows Remote Desktop as the remote control software.

Project Delays

The proposed remote cochlear implant mapping solution will require two approval processes. The first approval process is the Air Force DIACAP certification. The second approval process is an FDA approval. The both approval processes requires testing and documentation from only the manufacturers. Testing of this solution will require between six month and twelve months. The testing will only be conducted by the manufacturers and without human subjects, to meet FDA requirements. Currently, the manufactures are unsure if they will be able to dedicate the appropriate level of resources to the both of these approval processes. The project team is now investigating additional funding sources for the approval and implementation processes for the proposed remote cochlear implant mapping solution.

Telepathology

Clinical Implementation of Whole Slide Imaging (WSI)

This project was designed to not only demonstrate the utility of Whole Slide Imaging (WSI) as a technology, but also to show that WSI can be used reliably in the real-world clinical environment. In 2006, UPMC completed all deliverables associated with this project. A comprehensive final report covering Deliverables A, B, and C was prepared and delivered to the USAF SGR in July 2006. Deliverable D involved UPMC support for USAF attainment of DITSCAP certification for a digital pathology application that will be used as part of the FY 05 Telepathology Project (i.e. Trestle's MedMirco system). This proposal was awarded in June 2006. In December, 2006, the USAF was finalizing the remaining requirements for certification; therefore UPMC support was no longer required. UPMC sent a letter to Major Marsh as notification that this deliverable had been met in December 2006.

IMITS FY04 – Telepathology Project: SGR Deliverables

Deliverable	Hard Deliverable
<i>A. Telepathology: Clinical Implementation of Whole Slide Imaging</i>	
Requirements for whole slide image capture robot and barcode labeling integration	Included as part of Comprehensive Final Project Report
List of participants in working group with Radiology Informatics	Team List provided to SGR and also included as Appendix 1 in Comprehensive Final Project Report
Final report to include outcome of test/evaluation of whole slide image robots	Included as part of Comprehensive Final Project Report
<i>B. Telepathology: Improve Whole Slide Imaging Technology Performance</i>	
List of equipment purchased	Equipment List
Requirements for network simulation lab	Included as part of Comprehensive Final Project Report
Final findings to include evaluation and analysis and test/evaluation of existing systems on lab network	Included as part of Comprehensive Final Project Report
<i>C. Telepathology: Integration of Advanced Algorithm</i>	
Final findings to include identified requirements, outcome of acceptance testing, color calibration system results, data analysis, and other relevant findings	Included as part of Comprehensive Final Project Report

Deliverable	Hard Deliverable
<i>D. Telepathology: Integration of static, robotic and whole slide telepathology network</i>	
DITSCAP certification for Coolscope Dynamic Telepathology Application	DITSCAP Certification
Final report to include final ST&E testing and network implementation at all locations	

Reportable Outcomes

Publications

- Gilbertson, J.R., Ho, J., Anthony, L., Jukic, D.M., Yagi, Y. and Parwani, A.V. *Primary histologic diagnosis using automated whole slide imaging: a validation study.* BioMedical Central Clinical Pathology, 6(4).
- Gilbertson JR, Patel A. and Yagi Y. (2005). Clinical slide digitization: Whole slide imaging in clinical practice experience from the University of Pittsburgh. In J. Gu J. & R.W. Ogilvie (Eds). *Virtual Microscopy and Virtual Slides in Teaching, Diagnosis and Research*. (pp. 225-240). Boca Raton, FL: CRC Press.
- Ho., J., Parwani, A., Jukic, D., Yagi, Y., Anthony, L. and Gilbertson, J. (3/2006) *Use of whole slide imaging in surgical pathology quality assurance: design and pilot validation studies.* Human Pathology 37: 322 – 331.
- Yagi, Y. and Gilbertson, J.R., (2005) *Digital Imaging in pathology: the case for standardization.* Journal of Telemedicine and Telecare 11(3): 109-16.
- Yagi Y and Gilbertson J: *Speed, resolution, focus, and depth of field in whole slide imaging applications in clinical practice.* In J. Gu J. & R.W. Ogilvie (Eds). *Virtual Microscopy and Virtual Slides in Teaching, Diagnosis and Research*. (pp. 217-224). Boca Raton, FL: CRC Press.

Presentations

- Gilbertson, J. (1/2005) *Telepathology: A Digital Platform For Pathology.* IMITS Telepathology Meeting, Keesler AFB, Biloxi, MS.
- Zalme, R. Anthony, L., Hrzic, M., Kistler, M. and George, L. (3/2005) *IMITS Project and Telepathology.* Travis AFB, Fairfield, CA.
- Gilbertson, J. (3/2005) *Whole slide imaging: An update at the 2005 Lab Information Technology Summit.* Las Vegas, NV.
- Yagi, Y. (4/2005). *Telepathology Update.* 2005 ATA Special Interest Group Forum, Denver, CO.
- Yagi, Y. (4/2005). *Image Quality and Stain Analysis.* 2005 ATA Conference, Denver, CO.
- Zalme, R.C., Anthony, L., Gilbertson, J., Gadd, C., and Krills, S. (4/2005). *Integration of a Sophisticated Telepathology System into the Clinical Workflow of the Air Force.* 2005 American Telemedicine Association Conference. Denver, CO.
- Gilbertson, J.G. (4/2005) *Telepathology Update.* 2005 American Telemedicine Association Conference. Denver, CO.
- Jukic, D.M. ((8/2005) *Virtual Slide Imaging Clinical Applications: The Time is Now.* 2005 Advancing Practice, Instruction and Innovation through Informatics Conference, Lake Tahoe, CA.

- Gilbertson, J. (8/2005) *Whole Slide Imaging: Implementing a Platform for Digital Pathology*. 2005 Advancing Practice, Instruction and Innovation through Informatics Conference, Lake Tahoe, CA.
- Ho, J. (8/2005) *Clinical Implementation of WSI*. 2005 Advancing Practice, Instruction and Innovation through Informatics Conference, Lake Tahoe, CA.
- Jukic, D. (3/2006) *Virtual Imaging - Time is Now*. Wilford Hall Medical Center, Lackland AFB, San Antonio, TX.
- Ho, J., Jukic, D., Parwani, A. Anthony, L. Yagi, Y. and Gilbertson, J. (5/2006). *Validation of Whole Slide Imaging for Primary Diagnosis In Surgical Pathology*. 2006 ATA Conference, San Diego, CA.
- Yagi, Y. and Weinstein, R. (5/2006). *Telepathology: DICOM Pathology*. 2006 ATA Special Interest Group Forum. San Diego, CA.

Conclusions

The project was successfully implemented and the results are encouraging. The primary goals of this project were to evaluate whole slide imaging as a potential platform for pathology, and to advance the integration of telepathology systems at UPMC and the Air Force. It was hypothesized that digital slides could be implemented within existing workflows, and might be useful in establishing timely inter-facility diagnoses and consultations across multi-facility health systems.

Findings from our validation studies helped to verify that digital images are virtually identical to glass slide-based reviews of pathology cases. The results indicated that images produced by current devices have enough image information to allow pathologists to produce accurate, complex, and detailed diagnostic reports, even for difficult and complex cases. It is important to recognize that current images have significant limitations including areas of sub-optimal focus and artifacts that appear to be related to over-compression and limited dynamic range that can cause diagnostic confusion. These limitations must be kept in mind if digital pathology is to be used for routine clinical primary diagnosis or other clinical applications such as quality assurance or second opinion collaboration. Pathologists are beginning to understand these technologies more clearly and this understanding should allow pathologists to better use and manufacture superior systems in the future. Exactly when digital pathology will be accepted as a tool for clinical practice will depend on both advances in technology and mainstream acceptance of the value of digital pathology in clinical practice. Operating telepathology as a clinical service within a working medical center will require more than an imaging robot. In the experience of this project, factors such as the stability of the health system's network, the speed of servers, the performance of the pathologist's workstation and monitor, and even the functionality of the image presentation and navigation software proved more important and caused more difficulties for the pathologists than the performance of the imagers. While this project did not measure those parameters explicitly, it is clear that additional research is required. Furthermore, it appears that for telepathology to reach its potential, informatics groups will need to have better control across the entire IT environment, from imager to desktop, as well as image integration with the LIS.

In summary, current telepathology systems, especially whole slide imaging, seem capable of providing useful levels of surgical pathology reviews across distributed health systems and they will only improve over time. Future work in this field is required especially in slide navigation,

presentation speed, and data integration for digital pathology to research full potential in the clinical space.

Telepathology Static Image Implementation Evaluation Project

Gain information about perceived and actual barriers to and support for the adoption and use of the telepathology equipment and the interactive consultative process.

In 2006, UPMC completed all deliverables associated with the FY 02/04 Telepathology Static Image Implementation Evaluation Project. A comprehensive final evaluation report, ***IMITS Telepathology Project Static Image Implementation Research Study Final Evaluation Report***, was prepared and delivered to the USAF SGR in July, 2006, in conjunction with the FY 04 Telepathology Final Project Report. The final evaluation report was also submitted to the University of Pittsburgh IRB; Keesler, Eglin and Travis IRBs; and the Army HSRRB. This final report submission to the IRBs and the HSRRB officially closed the research activities associated with the Telepathology Projects.

Reportable Outcomes

Presentations

- George, L., and Barbee, S. (5/2006) *Exhibitor: Telepathology Demonstration Booth*. 2006 American Telemedicine Association Conference. San Diego, CA.
- Zalme, R.C., Jukic, J., Anthony, L., and George, L. (3/2006) *Overview of the project and the research study*. Lackland AFB, San Antonio. TX.
- Zalme, R.C. and George, L. (3/2006) *Exhibitor: Telepathology Demonstration Booth*. Society of Armed Forces Medical Laboratory Scientists (SAFMLS), Reno, NV.
- Zalme, R.C. (2/2006) *Telepathology in the DoD. (Discussion Forum)* 2006 Healthcare Information and Management Systems Society (HIMSS) Annual Conference and Exhibition, San Diego, CA.
- Zalme, R.C. and George, L. (10/2005) *Exhibitor: Telepathology Demonstration Booth*. Association of Military Surgeons of the United States (AMSUS), Nashville, TN
- Zalme, R.C., Anthony, L., Gilbertson, J., Gadd, C., and Krills, S. (4/2005) *Integration of a sophisticated telepathology system into the clinical workflow of the Air Force*. 2005 American Telemedicine Association Conference. Denver, CO.
- Zalme, R.C., George, L., Kistler, M., and Anthony, L. (3/2005). *Overview of the project and the research study*. Travis AFB, Fairfield, CA.

Conclusions

The evaluation component of the Static Image Implementation Project was approved by the University of Pittsburgh, Keesler, Eglin, Travis Air Force Base IRBs and the Army's HSRRB. The exempt approval process took one year to obtain. Efforts were made to reduce IRB approval redundancies since each governing institution required that we comply with the same code of federal regulations; however, each agency continued to require full submission and compliance with their processes. The time required to gain full approval to conduct research continues to be a barrier to project evaluations conducted by an outside objective agency (i.e., University of Pittsburgh) for research being implemented across numerous Air Force settings with funding channeled through the DoD (i.e., The US Army Medical Research Acquisition Activity – USAMRAA which serves as the contracting office for the IMITS projects.).

Implementation of the Static Image System was significantly delayed based on the requirements of the DITSCAP approval process, which took over a year. Although the time consuming certification process may have curbed user enthusiasm for this new technology, DITSCAP certification was still noted as one of the project's greatest accomplishments by post study survey respondents.

The lengthy DITSCAP certification process altered the original scope of the project which included progression of the technology from a static imaging system to one which included robotic microscopy and eventually whole slide imaging. Several lessons learned comments focused on the need to more adequately prepare for the certification process.

System utilization remained low throughout the study. Base level staff indicated that scheduling and time constraints prohibited involvement – time was required for staff to adapt to the technology and incorporate it into their workflow – time that they reportedly did not have. It was also noted that the project needed promoters and champions for successful adoption and use. It was recommended that, in the future, telepathology should become an Air Force priority with release time for interested staff to participate in project activities.

UPMC and the Air Force have benefited from the trials and tribulations of this project. Lessons learned will benefit the upcoming FY 05 Telepathology Project, which focuses on advancing the telepathology systems with deployment of robotic microscopy and whole slide imaging and the building of Air Force champions for telepathology.

FY 04 Telepathology Evaluation Project

Evaluate the impact of implementation and usage of WSI to perform Quality Assurance, Primary Diagnosis, and the value of using Immunohistochemical (IHC) Stains.

Impact of implementation and usage of WSI to perform Quality Assurance and Primary Diagnosis was assessed and reported as part of the final project report for the FY 04 Telepathology Project. Refer to project accomplishments, outcomes and conclusions above.

Research assessing the value of using WSI on immunohistochemical (IHC) stains will be completed as part of the FY 05 Telepathology Project.

Extra-Corporeal Membrane Oxygenation (ECMO)

Perform a needs assessment and planning initiative to develop a Pediatric ECMO Center in Hawaii for the Pacific Rim, leveraging UPMC's extensive knowledge and experience in this area.

As stated, the initial plan was to perform a needs assessment in the Pacific Rim to determine the feasibility of developing a regional Pediatric ECMO Center. Simultaneous to this IMITS agreement being signed, funding for an ECMO center was appropriated to the Army in Hawaii to develop a Pediatric ECMO Center. IMITS funded was directed to support this initiative and

equipment was purchased by UPMC with delivery to Hawaii in December 2005. A list of purchased equipment was sent to SGR, completing deliverable 1.

In March 2006, project deliverables were modified to include development of a research lab training protocol and a clinical protocol. Under the direction of Mark Ogino, MD from Kaiser, research training protocols and ECMO clinical applications were assessed and document development began with drafts of procedural checklists and training manuals. In April 2006, a research lab training protocol was completed and a copy submitted to SGR. This completed deliverable 2.

A research protocol was developed to assess the ECMO equipment and clinical processes. Beginning in September 2006, a series of clinical trials were conducted. Results of these trials were summarized in Appendix B, and will be used to guide development of the clinical protocol. This final clinical protocol is pending relocation of ECMO staff to Kapi'olani Women's Center, projected to occur in summer 2007.

Simulation and Training

Advanced Medical Education

Advanced Simulation for Medical Education and Training in the Pacific Rim Develop Medical Education capability with advanced medical simulators, leveraging expertise of UPMC's WISER Institute.

A detailed evaluation of the University of Hawaii's (UH) simulation requirements was conducted by members of the UH, UPMC, and University of Pittsburgh WISER Simulation Institute. The project team was able to develop a collaborative model to assist in the development of the UH simulation center. The collaborative team developed Memorandum of Agreement (MOAs) and licensing agreements to share curriculum and technologies. This collaborative process assisted in the design of the UH simulation center's hardware and software solution. The project team was able to use the University of Pittsburgh WISER Simulation Institute's SIMS application to effectively create a solution to deliver Internet based simulation and non-simulation training to UH. This solution is also compatible with the programs currently developed at the University of Pittsburgh WISER Simulation Institute. Upon completion of the solution, UH was able to requisition the required hardware and simulator equipment to complete the project. The system was implemented in October 2006. The results of the October implementation as well as the courses available at UH are outlined in Appendix C.

During this collaborative process, University of Pittsburgh WISER Simulation Institute members were able to identify existing partnerships between Asia and UH. UPMC and University of Pittsburgh WISER Simulation Institute were able to continue developing these partnerships to increase the UPMC WISER Institute exposure in Asia. Several members of the UPMC and University of Pittsburgh WISER Simulation Institute were invited to participate and present in the Annual Asia Pacific Military Medicine Conference in May 2006.

Simulation at Wilford Hall Medical Center

Conduct a “Needs Analysis” for incorporating simulation into the existing WHMC training programs

Site visits were held at San Antonio area simulation centers: US Army Medical Department (AMEDD) Center & School (Ft. Sam Houston), Wilford Hall Medical Center (WHMC), Brooke Army Medical Center, Ft Sam Houston (BAMC), Expeditionary Medical Support (MEDS) training site, Brooks City Base, Defense Military Readiness Training Institute, Ft. Sam Houston (DMRTI), University of Texas Health Science Center-San Antonio (UTHSC-SA), and the University of Pittsburgh WISER Simulation Institute. These visits were conducted to identify types of training provided, the capabilities of each center, and to analyze each center’s ability to expand services to meet increasing demand. Sustainability issues were also noted. Problems identified during these site visits include lack of integration with training and education requirements, short term or part-time personnel support, and adequate space.

A meeting was held in April 2005 with Maj Gen Bruce Green, Commander WHMC, who asked that the project focus on incorporating simulation into required training at WHMC. This would include a center using high-fidelity mannequins and virtual reality surgical trainers, that would primarily be Graduate Medical Education and Medical Readiness based. Also, basing the center at WHMC could help spread the use of simulation across the AFMS if outcome studies establish simulation as a valuable tool to conduct training.

The Pilot Simulation Center was started using equipment borrowed from the Laerdal Corporation and Medical Educational Technologies, Inc (METI) and one METI HPS simulator owned by WHMC. The equipment needed to conduct training for various programs, such as monitors, defibrillators, ventilators, and furniture, was acquired through Defense Reutilization and Marketing Office (DRMO), Ft. Sam Houston-(surplus but useable military medical equipment is turned in here and available at no cost to other military programs) at no cost to either WHMC or the IMITS Congressional cooperative agreement. Space in the main building at WHMC was allocated by the WHMC leadership and WHMC Space Committee in the ICU area of the hospital. The pilot center has been in operation since July 2005. Since the opening of the pilot center, over 1,500 students have received training in nearly 2,000 encounters.

Briefings and discussions were also held with WHMC Patient Safety Committee and the Chief of Hospital Services, the San Antonio Uniformed Services Health Education Consortium (SAUSHEC) Graduate Medical Education program directors and staff, the WHMC Medical Readiness Office, Readiness Skills Verification Program Managers, WHMC/UPMC Congressional Steering Committee, and WHMC Level 1 Trauma Center leadership and training staff. Suggestions from these groups are used during working group meetings to identify training opportunities that could be developed and used for data collection for the needs assessment. Methods for data collection include observations, discussions with stakeholders, training guidance, and literature reviews. Outcomes have included a study done on Pediatric Advanced Life support training outcomes and retention and reports from WHMC subsequently deployed to IRAQ following predeployment training.

The center has continued to grow steadily through 2006. Feedback has been very positive especially regarding “hands-on” skills practice compared to a classroom PowerPoint Presentation or briefing. The Pediatric residents have been using the center extensively to improve skills in the care of critically ill pediatric patients. The Pediatric ICU census has been steadily decreasing with less and less training availability on complex patients. The Pediatric ICU staff has also created a Conscious Sedation Verification Program using simulation of pediatric sedation cases. They have also used the simulation center for a resident study on compliance with PALS Protocols.

Readiness personnel have used the center for medical technician and nursing Readiness Skills Verification. In fact, the center will be used monthly to perform these checks on all skills rather than testing different skills on a tri-monthly rotating basis. The Emergency Department and Surgical Intensive Care Unit have used the center for all required annual skills testing. The Trauma Department has developed a pre-deployment trauma course that teaches critical deployment care skills using the Simulation Center. This pre-deployment course is built on the Emergency War Surgery Course and the feedback has been extremely favorable. Currently, the WHMC Pilot Simulation Center is awaiting feedback from the participants that have just been deployed. This feedback will be used to adjust, add, or delete subjects in the course.

The needs assessment was completed and submitted to SGR in June 2006 for review. The needs assessment incorporated the findings and the current observations from the pilot project. Both UPMC and WHMC stakeholders are pursuing several funding opportunities that will continue to fund not only the pilot simulation but also to establish a “center of excellence” in simulation training for the San Antonio Medical Center area.

“Patient Transfer” Simulation Training

Develop an innovative educational “Patient Transfer” simulation course

A detailed evaluation of the UPMC Nursing’s current training methods for the prevention of back-related injuries was conducted by members of the UMPC, the Beckwith Institute, and the University of Pittsburgh WISER Simulation Institute. The project team was able to obtain relevant information pertaining to the specific programs/training and the support structure required in preventing back-related injuries. From this evaluation, the project team was able to develop the course goals, objectives, curriculum, and educational tools. The course and the curriculum were incorporated in to the University of Pittsburgh WISER Institute’s SIMS application for both traditional and online training delivery methods. The course was designed for integration with high fidelity patient simulators and other mannequins designed for bio-mechanic and “patient” move simulations. Several evaluation and feedback methods were incorporated into the course materials. Evaluation methods such as pre and post patient transfer observations, trainee performance assessment tools, learning system effectiveness methods, programs leadership and support evaluations, instructor evaluations, and satisfaction surveys were be used. The course and the curriculum was completed and submitted to SGR in 2006.

Upon completion of the course design, a research study protocol was developed to accurately observe the effects of the course on the nursing participants. The protocol outlined a control

group and a treatment group. The control group will consist of one nursing unit that will only be supplied with tradition back injury prevention training through the Internet. The treatment group will consist of two nursing units that will receive the new course material. This protocol was approved by the University of Pittsburgh Institutional Review Board (IRB) in December 2006. This protocol will be submitted to the US Army Human Subject Review Board (HSRRB) as an expedited study, for second level review. HSRRB deferred their second level review requirement to SGR. The protocol is currently under review by the Air Force for second level approval.

The project team has completed all the evaluation observations listed: pre and post patient transfer observations, trainee performance assessment tools, learning system effectiveness methods, programs leadership and support evaluations, instructor evaluations, and satisfaction surveys. The project team has completed the analysis of the observations and will present the final report to SGR in the first quarter of 2007. Preliminary and final results were presented at several national conferences, listed in the key research accomplishments section, through 2006. The final results poster presentation can be reviewed in Appendix D.

Telemental Health

Explore opportunity for development of advanced telehealth applications for the treatment of post-traumatic stress disorders in mass casualty situations.

This project was put on hold and subsequently recommended for closure. During 2005, the Statement of Work (SOW) was reviewed and revised to include disaster response efforts, processes, and lessons learned from Hurricanes Katrina and Rita. The SOW was also to include fine-tuned processes required to adequately capture clinical, therapeutic, and logistical challenges. The Air Force Medical Service (AFMS) selected the appointed Principal Investigator (PI) to fulfill a senior leadership development position resulting in the Telemental Health Project being placed in a “Hold” status for several months. Subsequently the project was recommended to be closed as another PI was not presented and approved by the Wilford Hall Medical Center Congressional Review Board. This project was officially closed and reported to SGR as closed in 2006.

Platelet Gel

Create a model to evaluate the efficacy of Platelet Gel Therapy on non-healing diabetic foot wounds.

Members of WHMC and UPMC continued their participation in Platelet Gel project throughout 2006. The original study protocol was designed to demonstrate the safety and efficacy of Platelet Gel Therapy on non-healing diabetic lower extremity wounds. The study protocol, “A Randomized Prospective Multi-Centered, Investigator-blinded Trial of Platelet Rich Plasma (PRP) Gel Versus Control for the Treatment of Diabetic Neurotrophic Leg Ulcers”, was presented to the Office of the Air Force Surgeon General as part of the FY '05 Diabetes New Projects Proposal. This protocol was submitted to the Food and Drug Administration (FDA) in the third quarter of 2005; however, the original study protocol was not approved by the FDA in 2006. The study protocol may be approved if it is rewritten to address several concerns and requirements.

The Platelet Gel project team is continually negotiating with the FDA in order to receive approval to conduct the research study.

The original study protocol was going to examine only the use of Autologous Platelet Gel while observing its affect on wound healing rates among approximately four hundred patients. Based on the FDA's concerns, the study protocol has become more complex to account for additional requirements. The study protocol was modified to a pilot study of approximately sixty patients undergoing the following observations: Growth Factor Characterization of the patient's whole blood and the Autologous Platelet Gel, the efficacy of Autologous Platelet Gel, and the efficacy of Autologous Thrombin. The second version of the study protocol was completed in December 2006 and will be submitted to the FDA for approval in the first quarter of 2007. Once approval has been obtained, the project team will submit the research protocol for approval to the University of Pittsburgh Institutional Review Board (IRB), WHMC IRB, and the Office of the Surgeon General of the Air Force for second level approval.

Project Delays

The FDA denial of the research protocol has caused a delay of several months. Initially the FDA was unable to approve the research study by the close of 2006. The FDA requires several modifications to the research protocol that significantly affect the research study design. The Platelet Gel project team conducted several "Type C" meetings with the FDA in order to negotiate which items will require additional modification in order to gain final approval. This process delayed the initiation of the IRB approval process. The project team has completed the second version of the study protocol, which addresses all of the FDA's concerns and requirements. The study protocol will be submitted to the FDA for approval in the first quarter of 2007. Once FDA approval has been obtained, the project team will submit the research protocol for approval to the University of Pittsburgh IRB, WHMC IRB, and the Office of the Surgeon General of the Air Force for second level approval throughout 2007.

Teleophthalmology

Develop and implement an image transfer system and enterprise image archive for retinal images

With a focus on the workflow process, the project team at UPMC and Wilford Hall Medical Center worked to create a flexible modular mobile system and efficient workflow process. The core of the system is a laptop with adequate processing power and memory to act as a server with a SQL database, while the rest of the system is comprised of "stations" (such as registration, imaging, and consultation) that can be added, removed, or modified as needed to customize the workflow. Each station's function is worklist driven, which helps to eliminate typing errors and improves productivity. A server-generated unique identifier tracks patient movement through the stations. This movement may be non-sequential depending on the setting and system's configured layout. The unique identifier allows for tracking of workflow processes and may contribute to changes in the future. The retinal imaging station was configured using custom software. Imaging stations can be set up in a darkened area or tent with adequate space and ventilation for the patient, photographer, computer, and non-mydratic retinal camera. A consultation station can be set up for patients to discuss their images with a board certified ophthalmologist, who grades the images and recommendations for further treatment as indicated.

The user interface for importation of data files (JPG or DICOM) and unique identifiers for patients (meta-data) is complete. System software is in place for the transfer of images and meta-data to a designated server. The system's design will easily enable transfer of data packages to an enterprise digital image archive system or alternative servers in the future. Image reader screens for registration, imaging, and grading are in place. Refinements are being made as per team/user recommendation and/or evaluation feedback. Image grading tools and data mining and reporting tools are near completion. The system, initially field tested at a community health expo, is being used in two clinical settings at UPMC and at health fairs throughout the greater Pittsburgh area. IRB approved studies are being conducted across these facilities/settings, and findings are contributing to refinements to the system and workflow processes.

In December, 2006, the initial version of the software components for the teleophthalmology screening process was released. Over the next few months, the software will undergo final testing and refinement. The final version of the software will be completed by the end of the second quarter of 2007. This last step completes all project deliverables. A final project report will be issued to the SGR in spring, 2007.

IMITS FY04 – UPMC Telepathology Project: SGR Deliverables

Deliverable	Hard Deliverable
Image reading screens and software developed	Snap shots of software screens and database to be included in comprehensive final project report.
Copy of the feasibility study for integration of imaging with other IMITS projects (all should communicate with PACS)	Feasibility Study
Final report on development of image and metadata transfer system, and outcome of data analysis	Report

Reportable Outcomes

Presentations

- Wilson, R; Eller, A; Zgibor, J; Ward, J; Petrick, R; & Anthony, L. (5/2006) *Assessing the Capabilities and Effectiveness of a Teleophthalmology Screening Program*. Oral Presentation. 2006 ATA Conference, San Diego, CA.
- Uttecht, SD; Eller, A; Smail, J; Ward, J; & Chang, PJ. (5/2006). *Retinal Screening Workflow of the Populace at Health Fairs*. Oral Presentation. 2006 ATA Conference, San Diego, CA.
- Waller, S; Lane, G; Flynn, W; Ward, J; Eller, Bursell, SE; & Anthony, L. (5/2006). *Lessons Learned from a Teleophthalmology Program in the US Air Force*. Poster Presentation. 2006 ATA Conference, San Diego, CA.
- Eller, A; Chang, PJ; & Flynn, W. (5/2006) *IMITS Teleophthalmology Project: Seeing Tomorrow's Vision for the Future, Today*. Poster Presentation in UPMC Exhibit Area. 2006 ATA Conference, San Diego, CA.

Evaluation

Assess the capabilities and effectiveness of the technology and workflow process being created to support a Teleophthalmology screening program for diabetic retinopathy.

Observations

Three non-mydriatic retinal cameras were deployed in two types of settings. Two cameras were placed in the General Internal Medicine and the Diabetes and Endocrinology Clinics at UPMC Presbyterian and Montefiore Hospitals. The third camera was used in a mobile unit, which was made available to numerous rural and urban communities throughout the Pittsburgh area. Our tasks were to observe use of the cameras and to analyze computer generated data from the retinal screenings. Results were supplied to the appropriate leaders as the study progressed.

Community Outings

Starting in March of 2006, the evaluation team began attending community diabetic retinal screening activities with the mobile unit. These outings were used to gather information on project workflow. Workflow problems were identified and addressed with project leaders and personnel. In total, nine community outings were attended and the evaluation team's findings were reported for each site. At seven of these sites, surveys were given to patients who had finished being registered and imaged. The purpose of the survey was to monitor patient satisfaction. Eighty-six surveys were collected. Their results can be found in the Site Visit Reports.

See Appendix F:

- *Teleophthalmology Evaluation Team TopCon Camera and LAN Assembly Manual 2006*
- *Teleophthalmology Evaluation Team Site Visits 2006*
- *Teleophthalmology Evaluation Team Retinal Screening Program Survey 2006*

Clinical Breakfast Meetings/Focus Groups

In early spring 2006, breakfast meetings were held the General Internal Medicine Clinic and the Diabetes and Endocrinology Clinic. Both clinics recently began collecting images. The purpose was to introduce or reintroduce the availability of imaging personnel and to further explain the project to the nurses and MAs.

In September, 2006, focus groups were held with the two clinics in order to define ways of improving recruitment. Problem areas were identified by nurses and other health professionals, and suggestions for improving recruitment were noted and reported to project leaders. Once problem areas were rectified and the improvements made, recruitment in the clinics increased dramatically.

See Appendix F:

- *Teleophthalmology Evaluation Team Clinical Breakfast Meetings 2006*
- *Teleophthalmology Evaluation Team Clinical Focus Group Reports 2006*

Screening Activity Reports

Computer generated reports were used in clinic and community settings to calculate mean times for registering, imaging, and grading. 589 patients have been registered as of November 30, 2006, and 476 patients have had their images graded. Please note that these numbers include the patients seen at the *Healthy 4 Live/American Diabetes Association Expo*. Average total times for each of the sites are listed in the table below. Total time is the amount of time required for a patient to be registered, imaged, and their images graded.

Site (n)	Average Total Time (Minutes)
Community (272)	12.41
General Internal Medicine Clinic (113)	12.58
Falk Diabetes Clinic (91)	19.39

IRB Approval Process

In May of 2006, a modification to include the “Teleophthalmology Retinal Screening Program Survey” was submitted to the University of Pittsburgh IRB. The modification was approved on June 21, 2006.

Education

LEADERSHIP TRAINING

Provide recommendations for development of a leadership training program in the Air Force

During the spring of 2005, four Wilford Hall Medical Center Air Force officers attended pilot leadership training courses at the UPMC/Beckwith Institute. The Level One – Emerging Leaders course was attended by one WHMC medical officer and three Senior WHMC medical officers attended the Level Three –Strategic Leaders training under the pilot project. The USAF Point Papers/Travel Reports were collected and reviewed by WHMC and UPMC personnel to help with the evaluation of the courses.

In August 2005, at the request of the SGR this project was placed on hold. There were multiple factors influencing this decision including:

- Command changes at WHMC
- Level of funding support for USAF medical officer’s travel to support the pilot project at UPMC
- High Ops-Tempo of deployment requirements at WHMC to support both ongoing efforts in Central Command and other emergency humanitarian support efforts such as the response to Hurricanes Katrina and Rita

A new proposal was submitted to the Office of the Air Force Surgeon General in October 2005 for consideration of the project under a new Division/Directive. This project was officially closed and reported to SGR as closed in 2006, due the absence of any new consideration/funding.

Diabetes Self Management Tool

Develop and deploy a Diabetes Self Management Tool in the office setting leveraging existing technology at UPMC (Italy)

The original intent of this project was to take work performed in a separately funded congressional project on Diabetes and expand the associated technology to the Mediterranean. Due to unanticipated circumstances on the Diabetes project, the start-up was substantially delayed. It was determined that all resources needed to be focused on the conus diabetes project. Expansion to the Mediterranean could take place at another time. This project was officially closed and reported to SGR as closed in 2006.

Major Barriers

Development of Teleradiology-Load Balancing Distributed Radiology Statement of Work

The development and eventual agreement of the Teleradiology Statement of Work resulted after many months of discussion through 2005 and 2006. The most significant issues included the architecture definition and additional USAF administrative requirements, including the National Defense Authorization Act (NDAA) policies. The NDAA policies required a rewrite of the Teleradiology project Statement of Work.

Many conference calls and face-to-face meetings were conducted between the US Air Force and UPMC. It was a time consuming process to reach a final agreement on the architecture and new USAF administrative requirements. The Statement of Work was revised and agreed upon in April 2006. The new Statement of Work was submitted to the Air Force Surgeon General's Office as the FY05 Teleradiology proposal in May 2006 and awarded in September 2006.

Hurricane Katrina and impact on Keesler Air Force Base

In September 2005, Hurricane Katrina had a devastating impact on the Keesler Air Force Base. Much of Keesler AFB experienced significant salt-water damage and the hospital was not able to function for several months.

From September through December 2005, the Telepathology "Case of the Week" was put on hold. Fortunately, the telepathology equipment at Keesler Air Force Base was not damaged by the Hurricane. It was relocated to space in the "previous" Keesler emergency room. The Air Force pathology team did a tremendous job in getting the pathology equipment functioning again. They also led the effort to get the Telepathology "Case of the Week" started again. During January 2006, the first case was hosted by Keesler Air Force Base. In addition to problems experience by the affects of Hurricane Katrina on the "Case of the Week", the "Case of the Week" was postponed as a result of a new direction in virtual conferencing applications used by the Air Force. The Air Force has selected IBM SameTime. Member of the project team have

experienced problems with using this new application at Keesler Air Force Base during the fourth quarter of 2006. The project team is working diligently to resolve this issue to re-initiate the “Case of the Week”.

Manufacture Available Participation for TeleAudiology Project

The proposed remote cochlear implant mapping solution will require two approval processes. The first approval process is the Air Force DIACAP certification. The second approval process is an FDA approval. The both approval processes requires testing and documentation from only the manufacturers. Testing of this solution will require between six month and twelve months. The testing will only be conducted by the manufacturers and without human subjects, to meet FDA requirements. Currently, the manufactures are unsure if they will be able to dedicate the appropriate level of resources to the both of these approval processes. The project team is now investigating additional funding sources for the approval and implementation processes for the proposed remote cochlear implant mapping solution.

FDA Approval of the Platelet Gel Study Protocol

The FDA denial of the research protocol has caused a delay of several months. Initially the FDA was unable to approve the research study by the close of 2006. The FDA requires several modifications to the research protocol that significantly affect the research study design. The Platelet Gel project team conducted several “Type C” meetings with the FDA in order to negotiate which items will require additional modification in order to gain final approval. This process delayed the initiation of the IRB approval process. The project team has completed the second version of the study protocol, which addresses all of the FDA’s concerns and requirements. The study protocol will be submitted to the FDA for approval in the first quarter of 2007. Once FDA approval has been obtained, the project team will submit the research protocol for approval to the University of Pittsburgh IRB, WHMC IRB, and the Office of the Surgeon General of the Air Force for second level approval throughout 2007.

Key Research Accomplishments

Teleradiology

- Dynamic Workload Allocation Radiology Business Rules were developed, documented and agreed upon by UPMC and USAF.
- Dynamic Workload Allocation System Design developed, documented and agreed upon by UPMC and USAF.
- Key research and analysis of existing USAF technologies, including ICDB and Dictaphones Powerscribe system were conducted and documented.
- The FY05 Teleradiology proposal was submitted to SGR and awarded to UPMC.

Teleradiology Stentor Implementation Evaluation Study

- The exempt research protocol was approved by the University of Pittsburgh IRB, Wright-Patterson IRB, and the Army Human Subject Research Review Board (HSRRB).

- Pre-implementation interviews were conducted with seven radiologists, four clinicians, and four technologists.
- Post 3.1 interviews were conducted with four radiologists, three clinicians, and three technologists.
- Post 3.2.2 interviews were conducted with three radiologists, three clinicians, and three technologists.
- Project administrators contributed to project lessons learned.
- Baseline surveys were completed by 65 users (7 radiologists, 10 clinicians, and 48 technologists).
- Post 3.1 surveys were completed by 33 users (5 radiologists, 10 clinicians, and 18 technologists).
- Pulse surveys were completed by 44 users (Pulse 1 – 4 radiologists, 3 clinicians, and 6 technologists; Pulse 2 – 4 radiologists, 2 clinicians, and 3 technologists; and Pulse 3 – 4 radiologists, 3 clinicians, and 16 technologists).
- Post 3.2.2 surveys were completed by 30 users (5 radiologists, 10 clinicians, and 30 technologists).
- Project administrators contributed to lessons learned.
- Findings from interviews and surveys contributed to development and management decisions throughout the scope of the project.
- Wright-Patterson Medical Center diagnostic imaging patient volume-throughput figures increase significantly and remain high following deployment of Stentor.

Teleaudiology

- Determined the Audiologist and Otolaryngology surgeon subject matter experts from WHMC and UPMC and enrolled them as members of the project team.
- Continued involvement of the three US manufactures – Cochlear Americas, Advanced Bionics, and Med-EL, and obtained their participation in the project.
- Acquired letters of intent to participate from the manufactures.
- Evaluated the current requirements and procedures for cochlear implant mapping.
- Developed a working draft of the feasibility study for the proposed solution.
- Demoed the proposed solution using video conferencing equipment and remote control software at WHMC.
- Demoed and selected the preferred video conferencing equipment by Polycom.
- Order the preferred video conferencing equipment for WHMC (mobile responder).

Telepathology

- Developed and implemented a series of IRB approved controlled clinical validation studies.
- Published results from two of the validation studies in professional pathology journals.
- Orchestrated product demonstrations by select “Best in Class” high volume whole slide imaging systems to determine the state-of-the-art in commercial WSI technology.
- Developed recommendations for standards for barcode labeling, image storage and archiving, and related integrated processes that set the groundwork for developing a strategic plan for implementation of WSI at UPMC and in the USAF.

- Recommended process and equipment for continuous assessment and improvement of network configurations.
- Assessed requirements and tested a prototype system for a fully-integrated clinical WSI system.
- Performed web server load testing of UPMC network that resulted in improved network performance.
- Tested and reported recommendations for equipment and process for network monitoring and diagnostics.
- Developed and tested advanced algorithms for technical improvements to virtual image quality.
- Shared in formation of “Case of the Week” sessions between Air Force locations and UPMC.
- Supported AF efforts to obtain DITSCAP certification for their telepathology systems.
- Completed Static Image Implementation Research Study.

FY 02/04 Telepathology Static Image Implementation Evaluation Study

- The exempt research protocol was approved by the University of Pittsburgh IRB; Keesler, Eglin and Travis IRBs; and the Army Human Subject Research Review Board (HSRRB).
- Pre-implementation interviews were conducted with a subset of seven pathologists.
- Baseline surveys were completed by 15 pathologists and 12 support personnel.
- Intermittent surveys were completed by 8 pathologists and 2 support personnel.
- Lessons learned surveys were completed by 3 pathologists, 6 administrators, and 5 developers.
- An outcome of the low volume user activity reports and survey findings was the establishment of the interactive Case of the Week sessions. This online group forum provided pathologists with an opportunity to utilize their equipment and skills to capture static images and post cases for group presentations.

Extra-Corporeal Membrane Oxygenation (ECMO)

- The preferred list of equipment and the list of purchased equipment was sent to SGR.
- Equipment was delivered to Hawaii.
- Research lab training protocol was completed and a copy submitted to SGR.
- A research protocol was developed to assess the ECMO equipment and clinical processes.
- Clinical trials have begun.

Simulation and Training

Advanced Medical Education

- Developed a collaborative model to assist in the development of the University of Hawaii (UH) Center.
- Developed MOAs and licensing agreements to share curriculum and technologies.
- Continued efforts to enhance the existing Asia partnerships with UH to leverage other WISER or UH collaborations.
- Conducted two additional educational outreach programs for Asia.

- Identified and order hardware and software for the new UH Center that is compatible to that of UPMC.
- Completed UH design of the SIMS application.
- SimTiki is now officially open for student simulation and non-simulation training.
- Seven simulation courses and two non-simulation based courses are now available for UH via the UH version of the SIMS application.

Simulation at Wilford Hall Medical Center

- Needs assessment for WHMC simulation center was completed and provided to SGR.
- Additional site visits and assessments of San Antonio and National Sim Centers (WISER, USUHS, National Capital Center, and CSTARS, Baltimore).
- WHMC Simulation Working group established-including SAUSHEC, USAFSAM, Readiness Annual training, RSV managers, and UPMC.
- Continual identification of interested “users” and their needs identified.
- Pilot center space was expanded in WHMC ICU and equipped with existing WHMC mannequins, loaners, and excess property.
- 2000 simulation encounters (encounters are the number of times a person comes to the simulation center for example TNCC thirteen nurses for two days equals twenty six encounters).
- Trained approximately 1,500 students.
- WHMC Office of Personnel Management and Human Resources Committee have approved four simulation center civilian positions.

“Patient Transfer” Simulation Training

- Developed course goals, objectives, curriculum, and education tools.
- Developed evaluation and feedback methods.
- Developed research study protocol.
- Received University of Pittsburgh IRB approval for the study protocol.
- Submitted protocol to USAF for Second Level Approval.
- Completed all pre-training observations.
- Complete both the control and treatment groups’ participation in the nursing training on the new curriculum.
- Completed all post-training observations.
- Completed statistical analysis of all training observations.
- Completed the final report for submission to SGR
- Project featured in UPMC/IMITS Exhibit Booth at 2006 American Telemedicine Association (ATA) Annual Conference, San Diego, CA.
- Project featured in 2006 American Organization of Nurse Executives (AONE) Annual Conference, Atlanta, GA.
- Project featured in 2006 Institute for Healthcare Improvement (IHI) Annual Conference, Atlanta, GA.
- Project featured in 2006 American Association of Nurse Anesthetists poster presentation.

- Project featured in 2007 Society for Simulation in Healthcare (IMSH) Annual Conference, Orlando, FL.

Platelet Gel Therapy

- Submitted an Investigational Device Exemption (IDE) application to Food and Drug Administration (FDA) for the research study protocol in 2005. This version of the protocol was denied by the FDA in 2006 based on several requirements.
- The project team conducted research/analysis/meetings with the FDA, SGR, and UPDI in order to develop a new research study protocol that would fulfill the requirements of the FDA.
- Completed review of clinical trial studies designed to assess impact of autologous, blood derived wound healing products in order to develop a research study protocol (including platelet gel and thrombin).
- Completed research on existing evidence-based guidelines, position statements and expert opinions pertaining to growth factors in order to develop the new research study protocol.
- A new research study protocol was developed with the following new characteristics: Stratified Population, Growth Factor Characterization, Autologous Platelet Gel, and Autologous Thrombin.
- The new research study is complete and will be presented to the Office of the Air Force Surgeon General and the FDA for approval in the first quarter of 2007.

Teleophthalmology

- Completed software deliverables including registration, imaging, reporting, and data mining.
- Adjusted clinical workflow processes and increased monthly patient enrollment figures by over 300%.
- Two oral presentations and one poster presentations given at 2006 American Telemedicine Association (ATA) Annual Conference, San Diego, CA.
- Project featured in UPMC/IMITS Exhibit Booth at 2006 American Telemedicine Association (ATA) Annual Conference, San Diego, CA.

Education - Leadership Training

- This project was officially closed and reported to SGR as closed in 2006.

Reportable Outcomes

Please see Appendices for work product documentation.

Conclusions

The Air Force has benefited from the joint development and implementation of the multi-disciplinary IMITS Program initiatives. The IMITS program has gained momentum since it was

able to build upon the previous years of effort. During the next year, UPMC will complete all remaining deliverables for the FY04 IMITS projects. UPMC will continue to build upon the accomplishments of this past year to develop the deliverables required for the FY05 Teleradiology and Telepathology continuation projects.

- Evaluation activities were completed for the FY 02/04 Teleradiology Stentor Implementation Project and a final evaluation report was issued to the SGR, University of Pittsburgh IRB, Wright-Patterson IRB, and the Army HSRRB.
- All deliverables met on the Telepathology Project and a comprehensive final report was submitted to the SGR.
- Evaluation activities were completed for the FY 02/04 Telepathology Static Image Implementation Project and a final evaluation report was issued to the SGR; University of Pittsburgh IRB; Keesler, Travis and Eglin IRBs; and the Army HSRRB.
- The Teleophthalmology team completed several software deliverables and integrated these software components into the retinal imaging process. Patient enrollment figures increased dramatically following modifications to workflow processes implemented in clinical settings.
- The nursing simulation curriculum has provided guidance for UPMC and the Air Force on a training protocol to reduce nursing injuries as a result of improper movement of a patient.
- The launch of the SimTiki Simulation Center has provided simulation expertise found within UPMC to the University of Hawaii and the PacificRim.

Evaluation of these projects is ongoing. Preliminary response from the Air Force and UPMC has been positive. The benefits defined by the participants include improved productivity and quality.

References

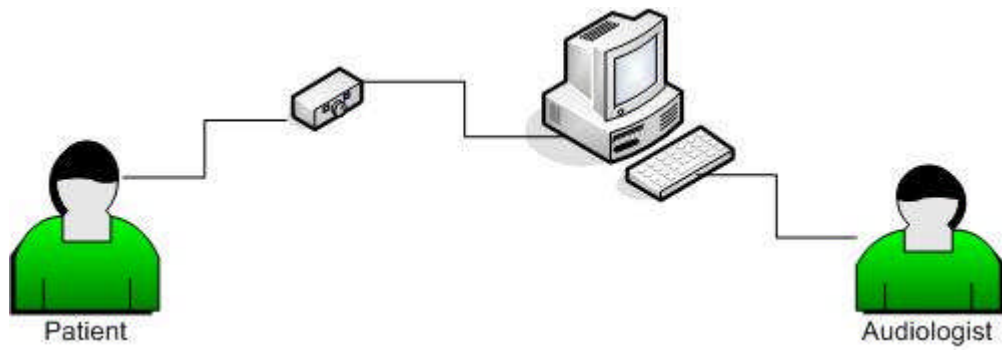
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Appendices

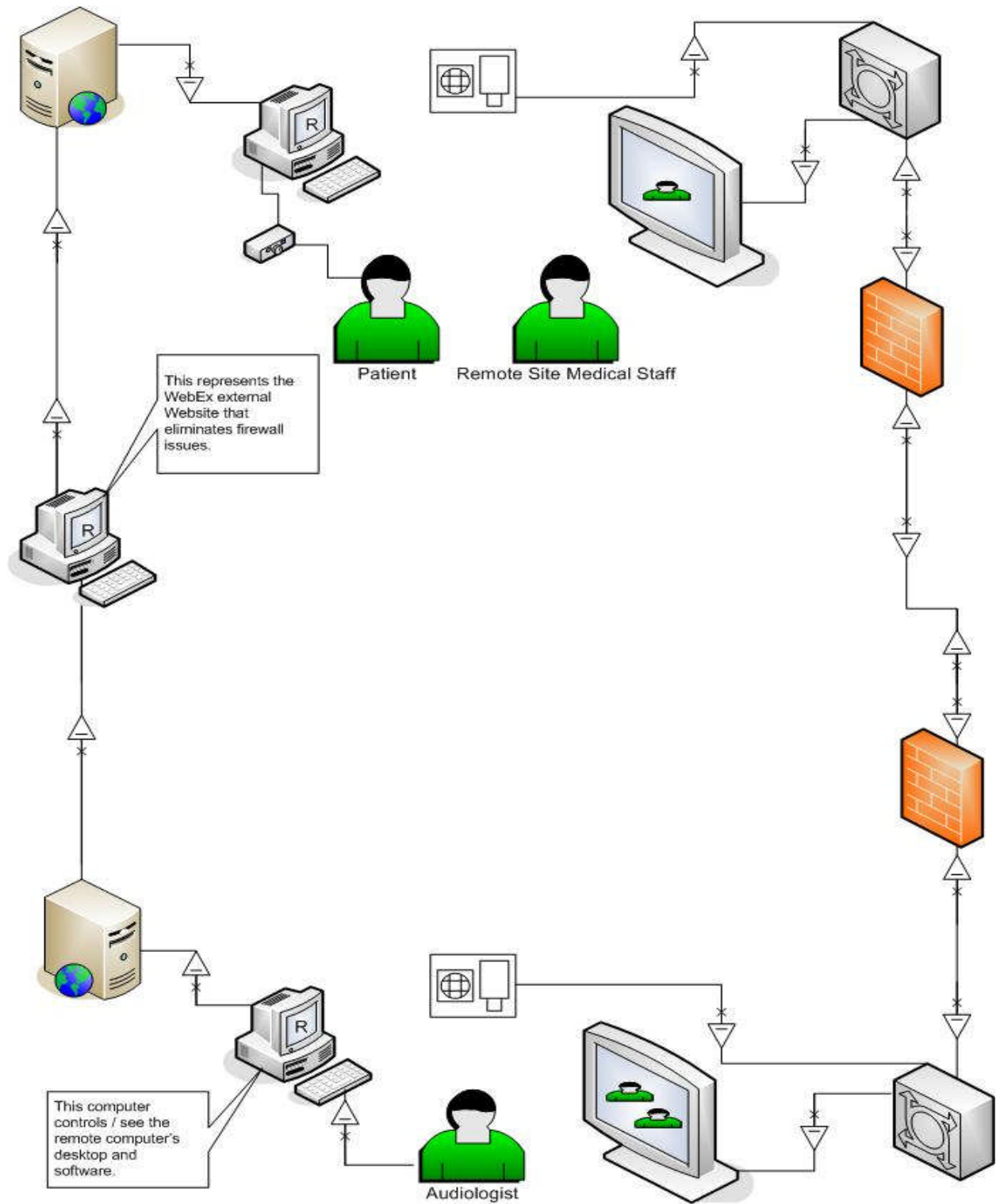
Appendix A

TeleAudiology

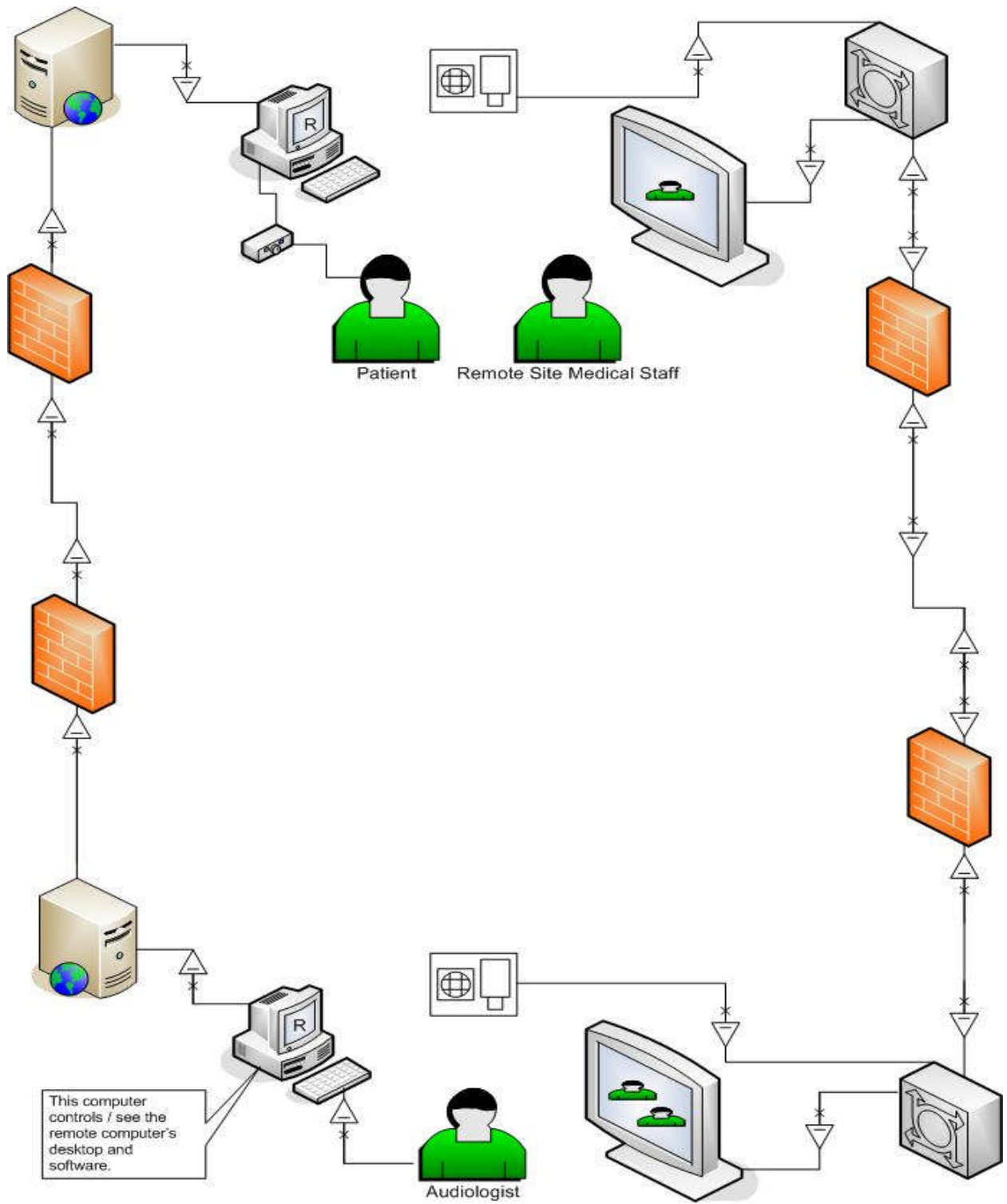
**Traditional Cochlear Implant Patient Access
(Patient in same room as audiologist)**



Remote (R) Cochlear Implant Patient Access – Web-based Software



Remote (R) Cochlear Implant Patient Access – Client/Server Software



Appendix B

ECMO



BioTronics, Inc.

Memo

To: Ralph Caputo

From: Melissa Mattes

Date: 2/23/2007

Re: The BioTronics perfusion team conducted a pilot study to examine the feasibility of a long term study that would examine the Jostra Rotaflow and its applicability to extracorporeal membrane oxygenation (ECMO). The rest of this memo is a summary of the study, the background leading into the study, and the results of the study. Formal reference citations can be provided upon request.

Purpose of the Study:

The goal of the study was to evaluate the latest generation centrifugal pump, the Jostra Rotaflow (Jostra Medizintechnik AG, Hirrlingen, Germany), to determine whether it can be used for neonatal ECMO and whether it might deliver a superior result with greater safety and improved outcomes than either the roller head or the earlier generation of centrifugal pumps provided. Our study was designed to look at hemolysis using this device and compare it against the hemolysis rate of a traditional roller head (Sarns 8000), and the Medtronic Biomedicus BP-50. The first phase of the study is a feasibility study to see if trends can be identified and to find any problems in the materials and methods before investing large amounts of funding. We will use plasma free hemoglobin generation as the indicator for hemolysis.

Background:

Extracorporeal Membrane Oxygenation, or ECMO, is a treatment modality for critically ill patients who have clinically reversible conditions but require support of their heart and/or lungs until the condition can be reversed. ECMO grew out of the discipline of perfusion in which the heart lung machine is used to support a patient during cardiac surgery. Patient selection and appropriate use of ECMO are major concerns. Another important concern is the appropriate use of new technologies.

The main components of the ECMO circuit are the pump and the oxygenator, which are connected with tubing and then connected to the patient's circulation system using cannulas. Throughout the years, the components have been changed and improved, safety devices have been added, and methods of monitoring have been refined.

The current gold standard for neonatal ECMO is the use of a roller pump as the propulsion device because it is simple, inexpensive, and familiar to most ECMOlogists. The roller pump, however, has many drawbacks. Occlusion of the outflow can result in high pressures, separation of the tubing, and catastrophic blood loss. Due to the extreme negative pressure that the roller pump exerts on the heart, a "bladder box" is needed to smooth the pressures out. Often these "bladder boxes" have areas of stagnation that produce clots risking the introduction of foreign particles to the circuit and the need to change the circuit. The roller heads are cumbersome and cannot be maneuvered in close to the patient necessitating long tubing, and

thus greater foreign surface contact. As the foreign surface area that the blood contacts increases, so does the possibility of thrombus creation, platelet damage, and complement activation, which then increases the blood requirements. During extended use, the constant rubbing of the roller on the tubing can cause spallation, or damage to the inside of the tubing. If this occurs, it may introduce foreign particles to the blood path, or risk tubing rupture, which in turn may result in catastrophic blood loss and air embolus introduction to the circuit. The early pioneers of the discipline discovered many of these pitfalls and began looking for ways to overcome them and safety devices that would alert them to impending problems. Pressure monitors on the arterial line were added to identify high pressures. Later improvements connected these pressure monitors to the roller heads to automatically stop the forward flow of blood if the pressure climbed too high. New generations of "bladder boxes" are being developed that minimize stagnation. Procedures have been developed, such as shifting the tubing in the head to insure that the pressure is not always on the same piece of tubing and eliminate the spallation effect. In addition to these changes in methodology, other changes were needed, most importantly, improvements in the equipment available for purchase.

Industry partners have worked with the clinicians to improve the equipment available, adding the requested safety devices to the equipment and developing high tech coatings for the inner surfaces of the components in order to minimize the impact of the foreign surface area on the blood components. Through out the years much effort has gone into developing a better pump. In the 1970s, centrifugal pumps were developed that utilized a variety of methods to impart kinetic energy to the blood that was then propelled from the centrifugal head through the circuit. In 1973, Medtronic (Medtronic Biomedicus, Inc. Eden Prairie, MN.) produced a disposable centrifugal head which allowed the new technology to be used for clinical procedures. This centrifugal pump consists of a series of concentric cones that spin when placed on the console due to its electromagnetic coupling. This spinning creates a negative force at the inflow which brings the blood into the cone. Once there, the cones impart the kinetic energy into the blood path and send the blood through the outflow of the cone. This method of blood propulsion was a benefit because it was afterload sensitive and occlusion of the outflow merely stops the flow rather than causes high pressure and all the resulting sequelae. No bladder box was deemed necessary with this generation of pump and it could be moved closer to the patient resulting in shorter lines, reduced foreign surface area, and reduced priming volume. However, the Biomedicus solved some problems and introduced others. Hemolysis generation is the primary concern when using this pump. The hemolysis is attributed to a variety of reasons including: the negative pressure generated at the inflow, length of time the blood spends in the cone, and heat generation from the electromagnetic coupling. Regardless of the reasoning behind it, it is common to change out the biohead while on ECMO every 4 days to minimize the hemolysis. Other concerns include inconsistent flow problems requiring a separate monitoring device, and a concern that the centrifugal pumps are not well paired with the Scimed (Medtronic Biomedicus, Inc. Eden Prairie, MN.) oxygenator which is the traditional ECMO oxygenator. The compatibility is a concern because of the high pressure requirements of the oxygenator, which is caused by its inherent resistance.

Now the next generation of centrifugal pumps is available. The Jostra Rotaflow (Jostra Medizintechnik AG, Hirrlingen, Germany) is one of the new generation. In this pump, the kinetic energy is created by a spinning rotor containing flow channels that direct the blood through the head and propel it through the circuit. With a single, non metal bearing for the rotor to rotate around, and a small priming volume, its product information reports that it has no areas of stagnation, less heat generation, and improved flow characteristics. Theoretically, these characteristics should have eliminated many of the disadvantages of the centrifugal pump; however, questions about the hemolytic properties of the early versions still persist. This is a grave concern because hemolysis, and its associated effects, remains one of the most common complications occurring in neonates undergoing ECMO. The Extracorporeal Life Support Organization's (ELSO) 2003 July Summary reports an incidence of hemolysis (as indicated by an elevated plasma-free hemoglobin >0.5 g/dL) to be in the order of 9.3% of all ECMO patients. Most authors have identified the method of blood propulsion as a major contributor to this hemolysis.

Previous Research:

Previous investigators have compared the roller pump to the Biomedicus pump and Jostra Rotaflow, the most notable among these being Duke Medical Center Lawson et al and Royal Children's Hospital Bennett et al. However, no one has looked at the neonatal ECMO scenario. The neonatal ECMO scenario is unique because it requires a low flow (1.5 liters per minute or less) that must pass through a high-pressure system (non-porous oxygenator) or through a low-pressure system (porous oxygenator). This lack of study has held back what could potentially be a quantum leap in both patient care and patient safety in the neonatal ECMO arena.

Study methods and materials:

Each run of the study was conducted on three separate circuits that each contained a different pump: the roller pump, the Biomedicus BP-50, or the Jostra Rotaflow. Each of the pumps was run in a circuit, constructed to closely mimic a high pressure clinical neonatal ECMO circuit, with a Scimed oxygenator (Avecor) and the ECMO^{therm} II heat exchanger (Medtronic) in line. The Scimed oxygenator is currently the only FDA approved oxygenator for ECMO. The tubing used was ¼ by 3/32 tubing. The circuit loop re-circulated through a one-liter bag. The circuit was primed with a unit of bovine blood, adding Plasmalyte to achieve a normal hematocrit and titrated with Sodium Bicarbonate to achieve a normal pH.

The three circuits are as follows: Circuit 1: The roller pump circuit is comprised of tubing that passes through a Sarns 8000 roller pump, and connects a 1500 Sci-med oxygenator, a heat exchanger, arterial pressure monitoring, sampling site, and a bag acting as a reservoir.

Circuit 2: The Rotaflow circuit is comprised of tubing, the Rotaflow, a 1500 Sci-med oxygenator, a heat exchanger, arterial pressure monitoring, sampling site, and a bag acting as a reservoir.

Circuit 3: The Biomedicus circuit is comprised of tubing, the Medtronic Biomedicus BP-50, a 1500 Sci-med oxygenator, a heat exchanger, arterial pressure monitoring, sampling site, and a bag acting as a reservoir.

These 3 separate circuits had simulated ECMO runs of six (6) hours apiece with each circuit, being run simultaneously with the same unit of blood. The trial was repeated three (3) times during this pilot study. These were labeled as run 1, run 2, and run 3. The occlusion on the roller pump was set using the gravity method. The circuits were primed with crystalloid and then with bovine blood. The target hematocrit was 30%. The blood was buffered with sodium bicarbonate to achieve the target blood gas. During the study, the blood was maintained at 37 degrees, Celsius. The blood gas parameters were as follows: pH of 7.30-7.45; pCO₂ of 35-45; and PaO₂ of 150-200. The flow was maintained during the 6 hour run at a rate of 300 ml /minute. A partial occluding clamp was applied to the arterial line to achieve a pressure of 300 Tor. All samples were taken from a stopcock after the dead space had been cleared and put into the green top tube required for plasma free hemoglobin testing. The plasma-free hemoglobin samples were collected at the same time on each of the three circuits for each run at the following time intervals: 10 minutes, 30 minutes, 60 minutes, 120 minutes, 180 minutes, 240 minutes, 300 minutes, and 360 minutes. The raw data was tabulated and analyzed with statistical software.

Results

Data for Run 1: Plasma free hemoglobin generated by each pump at specific time periods.

Time	Roller1	Jostra1	Bio1	Static1
10	55.5	234.7	524.6	19
30	178.4	361	759	17.9
60	254.8	428.9	899.3	18.3
120	373.3	543.9	1147	22.6
180	431.3	687.1	1263	19.4
240	520.2	780	1305	31.8
300	543	843.8	1338	36.2
360	584.5	917	1435	33.6

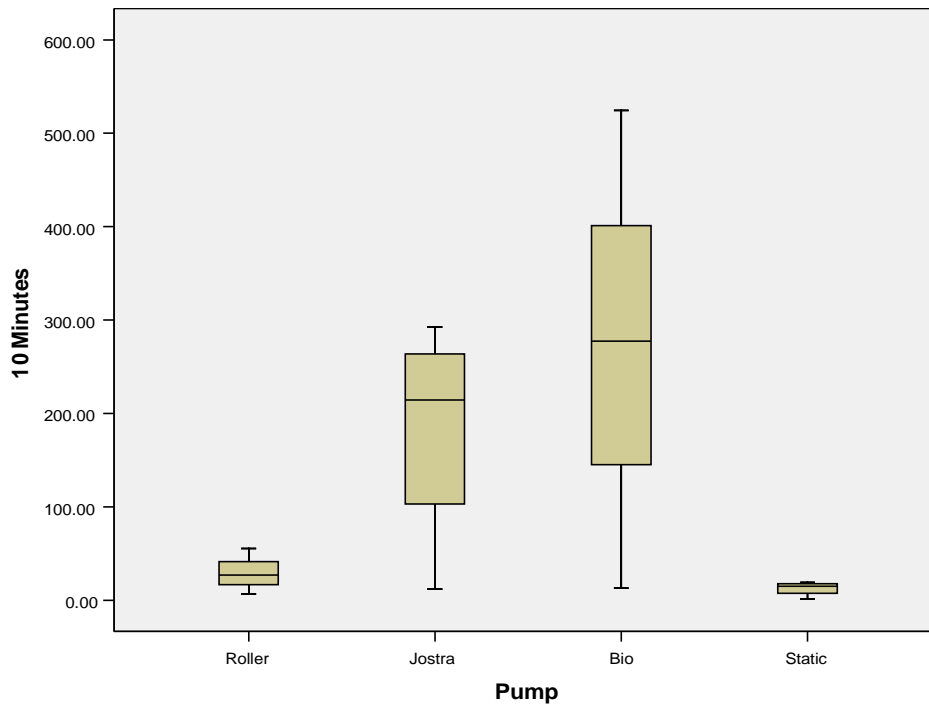
Data for Run 2: Plasma free hemoglobin generated by each pump at specific time periods.

Time	Roller2	Jostra2	Bio2	Static2
10	27.3	193.8	281.6	16
30	50.9	345.2	365.8	14.4
60	97.4	486.1	438.1	17.8
120	219.8	679.6	615.2	22.1
180	351.6	838.5		22.3
240	462.8	930.8	862.7	18.2
300	532	970.5	1003	22.6
360	662.5	1057	1089	18.4

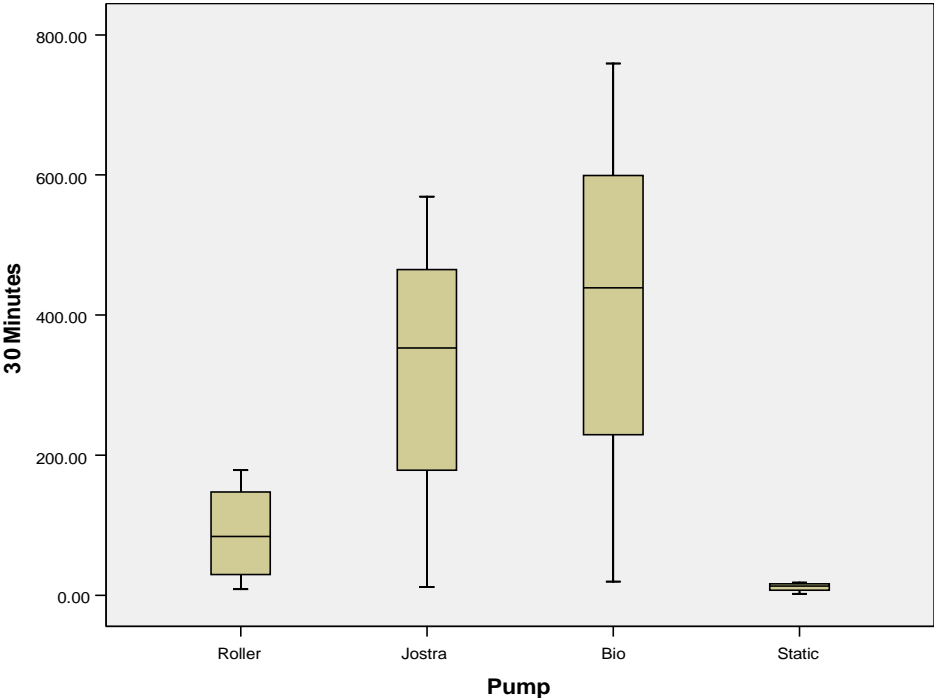
Data for Run 3: Plasma free hemoglobin generated by each pump at specific time periods.

Time	Roller3	Jostra3	Bio3	Static3
10	26.5	292.6	277.3	13.7
30	116.5	569.2	439.1	11.7
60	472.2	754.6	602.1	20.2
120	1398	1009	769.7	14.6
180	2163	1203	927.9	22.7
240	2759	1264	1025	19.6
300	3100	1407	1008	18.9
360	3337	1532	1134	19.4

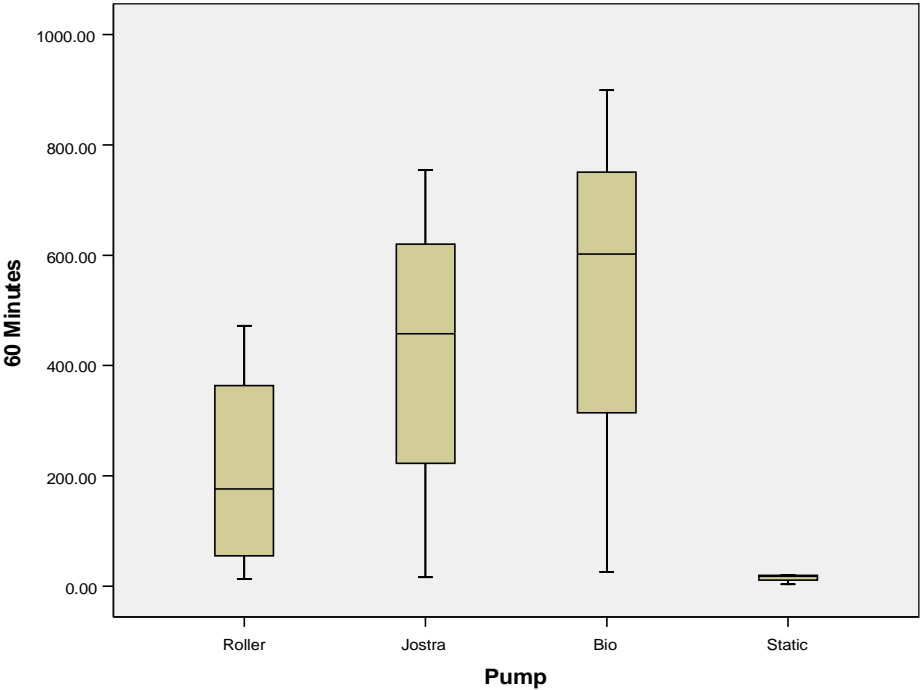
Graph 1: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 10 minutes. Displayed with variance.



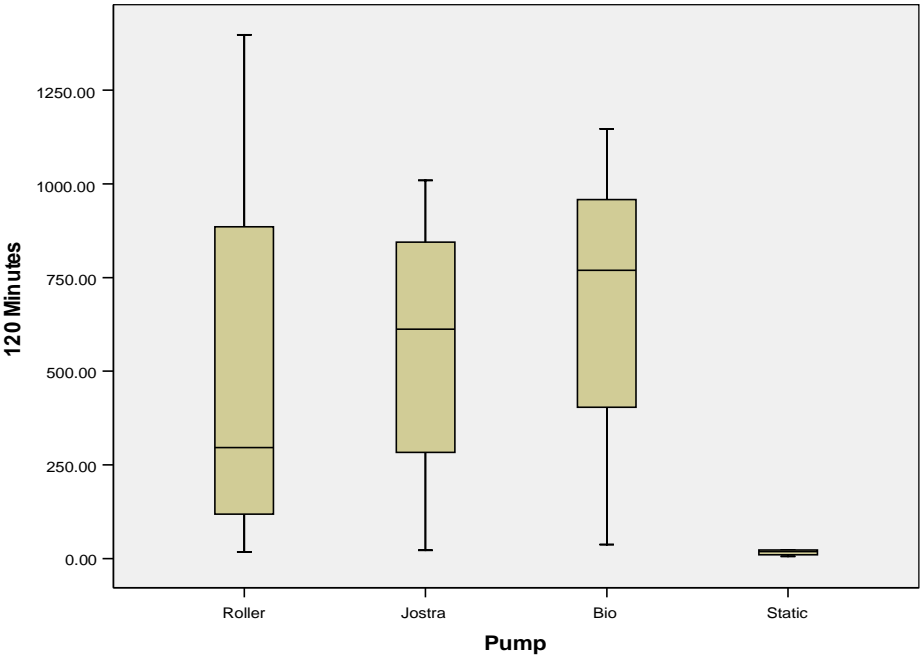
Graph 2: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 30 minutes. Displayed with variance.



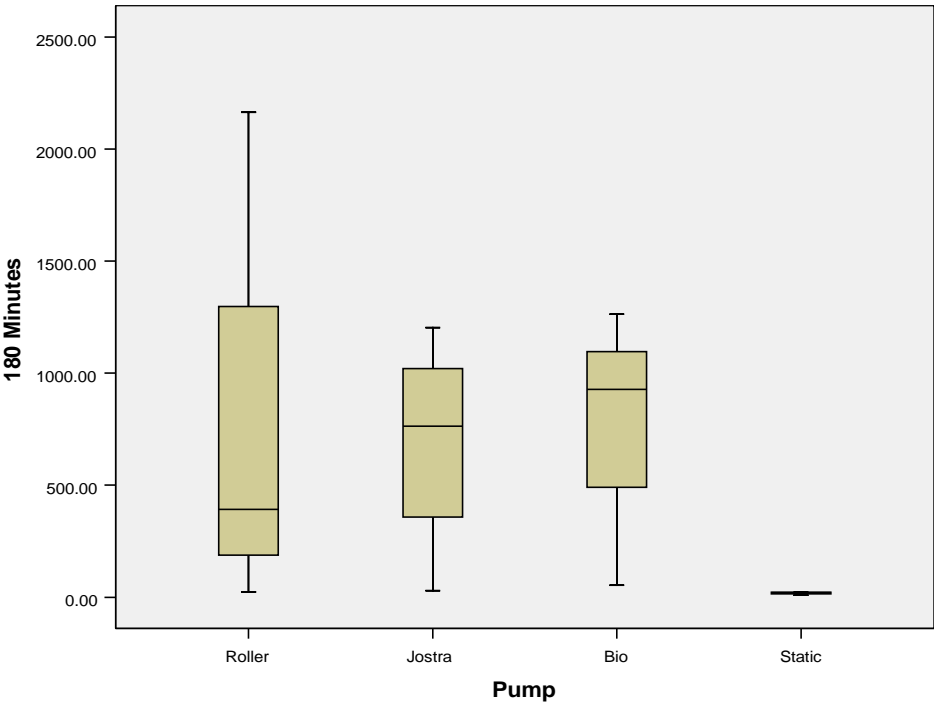
Graph 3: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 60 minutes. Displayed with variance.



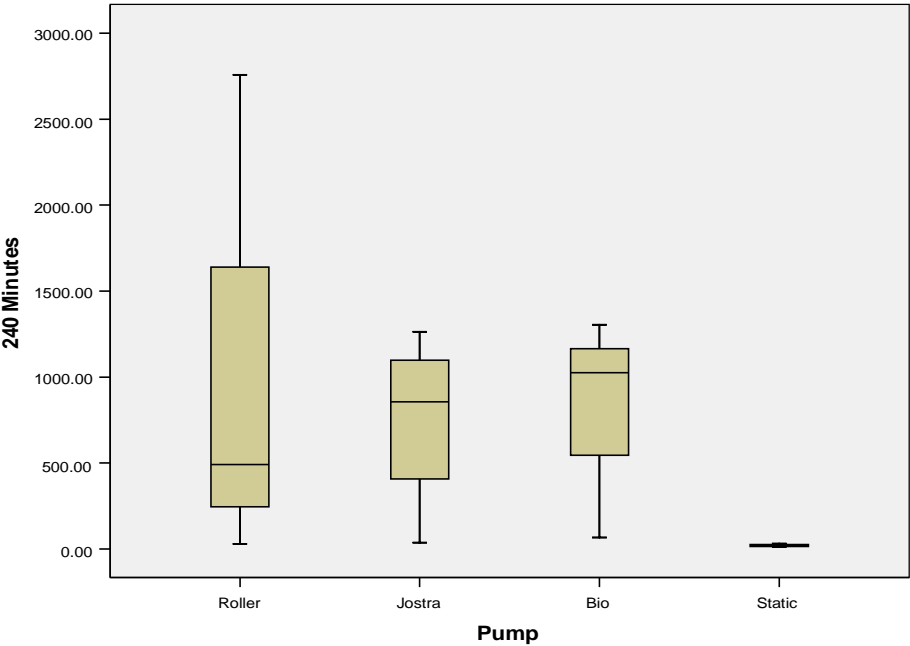
Graph 4: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 120 minutes. Displayed with variance.



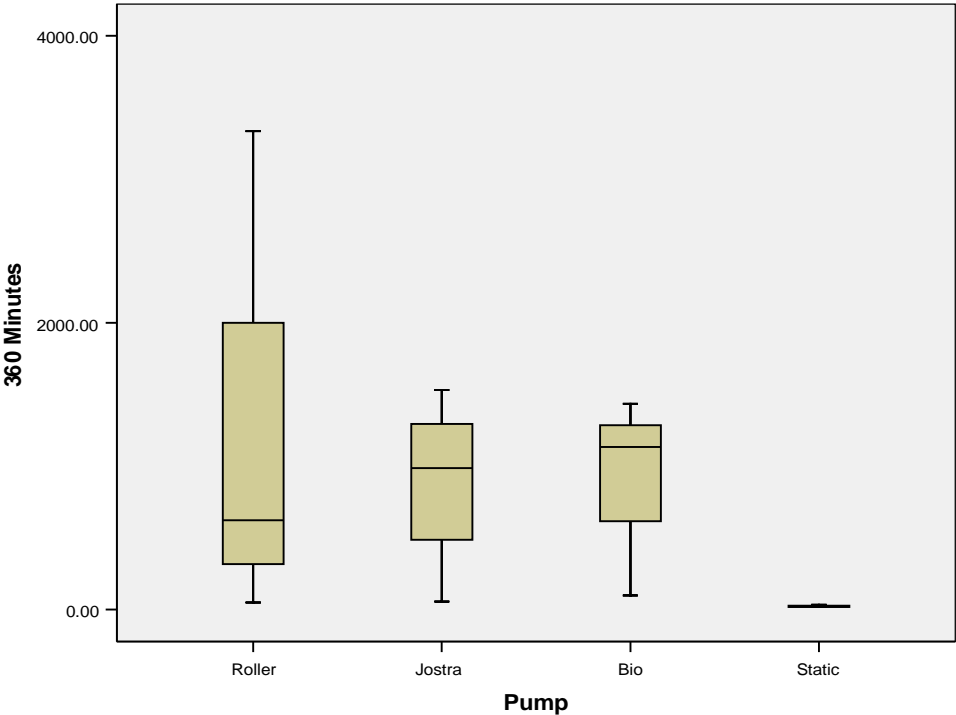
Graph 5: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 180 minutes. Displayed with variance.



Graph 6: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 240 minutes. Displayed with variance.



Graph 7: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 300 minutes. Displayed with variance.



Discussion

Since ECMO is a therapy that serves a small population of critically ill patients, there is high morbidity and mortality associated with the procedure. As such, it is incumbent upon the caregivers to explore new equipment and procedures to identify components and methods that may improve the outcomes of their patients. We believe that the latest generation centrifugal pump, Jostra Rotaflow (Jostra Medizintechnik AG, Hirrlingen, Germany), can be used for neonatal ECMO and will deliver a superior result with greater safety than either of the two pumps that are currently employed most frequently for ECMO in the United States of America.

In our study we looked at the hemolysis of the Jostra Rotaflow compared to the hemolysis of a traditional roller head (Sarns 8000) and the Medtronic Biomedicus BP-50. We selected to start with a pilot study due to the expense of the equipment. We wanted to know whether the methods employed in this equipment study were feasible. However, due to the limited data set, the results must be examined with caution. Our interpretation was further complicated by large variance, particularly in the third run. We suspect this variance was due to the nature of the blood sample used in that run. A larger study would allow a run of this nature to be identified as the result of an unexpected trend, or as an outlier. With the size of the study, we are unable to identify these points as outliers with any certainty.

Although the limited data set and the variance do not allow for a statistically significant comparison, it is useful to note that the order of the means is consistent across all time periods, as demonstrated by graphs 1 – 7, and is in the direction that was anticipated with the roller head producing the smallest amount of hemolysis, the Rotaflow the next lowest level, and the Biomedicus pump producing the greatest hemolysis. These results are promising and suggest that the subject should be subjected to a more rigorous examination.

If continued study bears out these trends, it would be our suggestion that the Jostra Rotaflow would be appropriate for all ECMO patients except for the following cases:

1. Patients who have Congenital Diaphragmatic Hernias and will require a prolonged ECMO run.
2. Patients who have Pulmonary Hypoplasia and will require a prolonged ECMO run
3. Patients between 5 & 10 kg
4. Other patients for whom the ECMO run is presumed to last more than a week as determined by the attending ECMO physician.

These four types of cases would be conducted on a roller pump that at this point appears to have the lowest generation rate of plasma free hemoglobin.

Moving all other cases to utilizing the Jostra Rotaflow allows for the prime of the circuit to be minimized, thus minimizing the impact of foreign surface area on the blood components, and minimizing the patient's exposure to blood products. It also provides improved safety, and would facilitate transportation of a patient on ECMO.

Regarding the feasibility of the methods of the study, we found that the circuits and methods were acceptable and would suggest using them in a larger study. However, before undertaking a study that would provide larger numbers and incur greater expenses, a fresh, locally available blood source would need to be identified and procured.

Future studies

In October, the FDA approved a new generation of membrane oxygenator, specifically Jostra's Quadrox D, for use in the United States. In the educational material that accompanies the product, the manufacturer explains that the Quadrox D is comprised of two membranes, the first of which contains both a sheet of heat exchanger fibers and a sheet of diffusion oxygenation fibers. The second membrane is entirely oxygenation fibers. The oxygenation fiber being used is a true diffusion membrane that only allows diffusion of the gas molecules across the membrane in the direction of the concentration gradient. As such, it acts as a solid barrier, and plasma leaks will not occur. These characteristics will make the Quadrox D ideal for ECMO. It also has lower pressure requirements that the Scimed oxygenator and will be more compatible with the Rotaflow.

Future studies should investigate the plasma free hemoglobin generation of the three pumps, the roller head, the Jostra Rotaflow, and the Biomedicus BP-50 in combination with the

newly released Quadrox D oxygenator to compare their hemolytic properties. This would provide research based evidence to back up the anecdotal evidence coming from international ECMO institutions that indicates that the pairing of the Rotaflow with the new generation of oxygenator will produce a sophisticated system which can improve the patient outcomes for ECMO.

Appendix C

Advanced Medical Education

Recap of WISER SimTiki Site visit on October 9-12, 2006

WISER faculty Paul Phrampus and John Lutz visited the University of Hawaii simulation center, SimTiki from October 9 through 12, 2006. During that time, they conducted a site review and identified numerous collaborative projects to work on in the future. This report reviews that visit.

SimTiki facility

SimTiki is located on the second floor of the Medical Education Building at the University of Hawaii (UH) John A. Burns School of Medicine. There is 1 large simulation room with 2 Laerdal SimMan & 1 METI Human Patient Simulator. This room is outfitted with video cameras and microphones to record simulation sessions onto video tape. There is another room that contains an Immersion Endoscopy Accutouch simulator, an Immersion Laparoscopic Surgical Workstation, a laparoscopic simulator that was developed in-house, and a virtual reality (VR) simulator, utilizing goggles, headphones and VR gloves. The VR simulator was also developed in-house. There is a control room between the two simulation rooms with one-way mirrored windows between the simulation rooms and the control room. The control room houses the audio and visual components.

UH also has a large teleconference room on the same floor that utilizes Access Grid software. This software allows multiple simultaneous high speed video conferences utilizing the Internet2 network. The Pittsburgh Supercomputing Center also has an Access Grid node, so this will be explored as a possible collaborative project (see below).

There are multiple conference rooms throughout the office space. There are also numerous empty offices and cubicles that the Telehealth Research Institute (TRI) program (under which SimTiki sits) hopes to utilize with collaborative entities.

Collocated on the second floor is the Objective Structured Clinical Examination (OSCE) Center for the UH School of Medicine. While SimTiki is not directly involved in the OSCE program at the UH, there is possible future collaborations here. There are approximately 10 patient exam rooms with audio and video recording equipment. Patient interactions can be viewed live or recorded on PCs in a central review room.

Collaborative Projects

The following is a list of projects that were discussed and seem to provide excellent collaborative possibilities.

- Ft. Sam / Ft. Irwin
Discussed the next steps to move the Ft. Sam / Ft. Irwin project forward
- Crisis Team Training – Rapid Response Course
There is significant interest in having the CTT course run at SimTiki. Paul will discuss with Mike Devita to get this moving forward
- SimTiki grand opening in February
SimTiki will hold a conference in February to mark its official opening. There will be presentations, etc. John & Paul plan on going. Funding will be available to pay for the trip.
- APPMC in Manila. The Asia Pacific Military Medicine Conference will be held in Manila this year. Paul & John will present in a similar manner to what they did in New Delhi this year. Funding will be available to pay for this trip as well.
- Audience Response System
Ben & Dale have been utilizing the TurningPoint (TP) audience response system (<http://www.turningtechnologies.com>). We have identified a number of projects to use this system. There are three research projects that will utilize this system: Vital Sign reliability, Transcutaneous pacing, and task distribution with novices. Essentially each project will involve a group watching a

live simulation or video presentation and using the (TP) keypad to respond to prompts. The exact protocols for each of the projects will be developed in the near future.

Another project is integrating the TP system into SIMS. We have purchased the TP system at WISER and are currently integrating the two together.

- Video Laryngoscope
Ben & Dale have been using the Video Laryngoscope (VL), developed by the Karl Storz company, and in collaboration with Ben Boedeker from the University of Nebraska. Ben Boedeker has developed curriculum for the VL, which will be deployed via SIMS on the Medical Education Consortium Center for Advanced Technology web site (www.medccat.org).
- ECMO
We met on the ECMO project. Larry outlined the funding for this project and started to develop tasks and who would work on them. We also met with Anne Naclerio, who is developing nursing critical care curriculum as part of this project.
- MET integration into SIMS
SimTiki utilizes at METI HPS simulator. We will work to download data from the simulator into SIMS in a fashion similar to what we do with SimMan now.
- Access Grid
We will look at opportunities to utilize the Access Grid in for remote training. The Pittsburgh Supercomputing Center has an Access Grid center on South Craig St. John has contacted them to see if we can utilize that system.

Courses on the SimTiki Web site:

Fundamental of Critical Care Support:

This is a two day course which begins on the date(s) identified above.

Course Purpose

- To better prepare the non-intensivist for the first 24 hours of management of the critically ill and injured patient until transfer or appropriate critical care consultation can be arranged.
- To assist the non-intensivist in dealing with sudden deterioration of the critically ill and injured patient.
- To prepare house staff for ICU coverage.
- To prepare nurses and other critical care practitioners to deal with acute deterioration in the critically ill and injured patient.

Course Objectives

- Prioritize assessment needs for the critically ill and injured patient.
- Select appropriate diagnostic tests.
- Identify and respond to significant changes in the unstable patient.
- Recognize and initiate management of acute life-threatening conditions.
- Determine the need for expert consultation and/or patient transfer and prepare the practitioner for optimally accomplishing transfer

JABSOM - Airway Management Course I:

This course will introduce student to basic and advanced concepts of airway management utilizing didactic and simulation based practical experience with a variety of airway devices and techniques. Advanced material includes the following focus areas:

- Airway management in mass casualty
- Obstetric airway management
- Pediatric Airway management
- Supraglottic airway management
- Airway management complications
- Airway in trauma
- Difficult airway evaluation
- Advanced airway techniques I & II
- Airway in the ICU
- Out of operating room airway management
- Advanced masking techniques
- Flexible fiberoptic intubation

JABSOM MS3 - Surgery Trauma Program I:

Course Purpose

- To provide an introduction to basic principles of trauma management
- To augment the American College of Surgeons core medical student TEAM Curriculum with high fidelity manikin based curriculum.
- To support the research project: Outcomes Assessment in a Simulator-Based Trauma Curriculum: Use of Scenario Development.

Course Objectives

- Prioritize assessment and management strategies for trauma patients using the ABCDE approach
- Demonstrate knowledge of basic principles through manikin trauma scenario management.
- Complete one scenario development exercise

JABSOM MS3 - Surgery Trauma Program II:

Course Purpose

Session II of the MS3 JABSOM Surgery trauma Curriculum

- To provide an introduction to basic principles of trauma management
- To augment the American College of Surgeons core medical student TEAM Curriculum with high fidelity manikin based curriculum.
- To support the research project: Outcomes Assessment in a Simulator-Based Trauma Curriculum: Use of Scenario Development.

Course Objectives

- Prioritize assessment and management strategies for trauma patients using the ABCDE approach
- Demonstrate knowledge of basic principles through manikin trauma scenario management.
- Complete one scenario development exercise

JABSOM MS4 - Emergency Medicine Skills Lab I:

This course is a required element of the JABSOM MS4 Emergency Medicine rotation. The session will utilize manikin based simulation techniques and didactic lectures for instruction in the following focus areas:

- Introduction to Emergency Medicine
- Airway Management
- Respiratory emergencies
- Chest pain evaluation and management
- 12 Lead EKG Interpretation

JABSOM MS4 - Emergency Medicine Skills Lab II:

This course is a required element of the JABSOM MS4 Emergency Medicine rotation. The session will utilize manikin based simulation techniques and didactic lectures for instruction in the following focus areas:

- Altered Mental Status
- Toxicology
- Shock
- Trauma

There are also plans to have the CTT course that is taught at WISER to be rolled out to SimTiki ASAP.

Appendix D
“Patient Transfer”
Simulation Training

Development of a Simulation and Internet Based Pilot Intervention to Evaluate Adherence to a Patient Transfer Protocol in the Real World Environment

John O'Donnell, Judith Bradle, Joseph Goode, Claire Daday, Edward Cook Beth Oswald, Jennifer Fleegle, SuAnne Caccamese, Dennis Martin, John Close, John Lutz, Angela Moczan

Peter M. Winter Institute for Simulation, Education and Research (WISER) Pittsburgh, PA 15213

University of Pittsburgh
and the
University of Pittsburgh Medical Center

INTRODUCTION

- Nursing back injury is epidemic:** The average age of nurses is > 45 with 80% expected to have at least 1 significant back or musculoskeletal injury during their career. Nursing personnel are # 2 behind truck drivers in work related musculoskeletal injury (Bureau of Labor Statistics 2002)
- Financial impact:** Nationally, the cost of nursing injury is estimated to be billions of dollars with 5% of patients responsible for up to 95% of overall expenditures
- Key barriers to safe and effective moves:** Inadequate orientation or lack of on-going training; perception of inadequate time, tools or people; physical fitness of staff; failure to assess patients' ability or engage them to help; lack of knowledge of true toll of injury
- Funding:** Project sponsored by funding from the USAF, administered by the US Army Medical Research Acquisition Activity, Ft. Detrick, MD (Award # DAMD 17-03-2-0017)

METHODS

- Primary Aim:** To improve direct patient care personnel skills and adherence according to a 10 point transfer protocol using an internet and simulation-based training program
- Design:** Prospective educational intervention conducted as a pilot study at the University of Pittsburgh and the University of Pittsburgh Medical Center (IRB# 0511041)
- Hierarchical Task Analysis:** Deconstructed transfer processes in consultation with certified ergonomic experts and direct care providers. Developed a universally applicable 10 point transfer protocol to be used as a primary measurement instrument
- Transfer Data:** Observed and scored transfers on four nursing units of the UPMC Institute for Rehabilitation and Research at UPMC South Side and UPMC St. Margaret and also during simulation training scenarios at WISER
- Data Collection:** Automated through use of HP IPAQ™ devices, Laerdal SimMan™ log files and through the WISER Simulation Information Management System (SIMS)

Key Program Elements

- 'Real-world' data collection pre- and post intervention
- Automated subject assessment using SIMS
- WISER supported internet based curriculum and instruction
- Ergonomic focused Simulation intervention
- Immediate feedback & correction
- Quantitatively measured transference of simulated to real-world skills

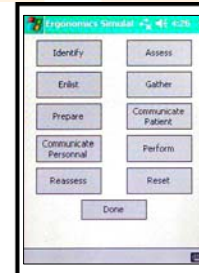
10 Point Protocol

1. Identify Patient & Move Requirements
2. Assess Patient
3. Enlist Personnel
4. Gather Equipment
5. Prepare Environment
6. Communicate to Patient
7. Communicate to Personnel
8. Perform Move
9. Reassess Patient
10. Reset Environment

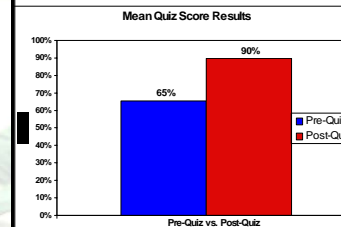
RESULTS

Development of Validity & Reliability

- Protocol steps were developed through expert consensus as well as referencing to practice standards or best evidence.
- Coders were trained by experts across 10 transfer events in the clinical environment
- Cohen's *kappa* was calculated for each of the 10 protocol steps with mean of 0.62 (range 0.43- 0.83) indicating substantial inter-rater agreement across the protocol

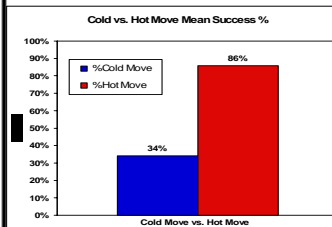


Improved Knowledge



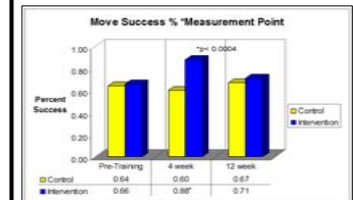
- Used a classic pre-test, post-test design
- 10 quiz items administered (pre & post)
- Paired t-test compared pre & post %
- N= 67 pairs, $t_{66,05} = -11.21$, $p \leq 0.0004$

Improved Simulated Skills



- 19 teams with each team performing 4 simulated moves (2 'cold' + 2 'hot')
- Paired t-test compared pre and post %
- N= 19 pairs, $t_{18,05} = -14.76$, $p \leq 0.0004$

Improved Real World Skills



- Observed real world patients transfers (n= 306) with observation at three time points (pre-intervention, 4 wk, 12 wk)
- Significant improvement in transfer skills observed at 4 week time point on intervention unit ($p \leq 0.0004$)

CONCLUSIONS

- Curricular Effectiveness:** Internet curriculum combined with hands on training using a low fidelity simulator (Laerdal TuffKelly Move Mannequin™) + structured protocol was effective for improvement of knowledge. Improved transfer skills were demonstrated across the protocol and in each 10 point transfer protocol step
- Satisfaction:** Subjects reacted positively and demonstrated a high level of satisfaction with the intervention both at the end of the simulation training and at the 4 week follow-up measurement point
- Retention:** Follow-up real world patient transfer observations at 4 weeks demonstrated significant improvement from baseline in adherence to the steps of the 10 point protocol. Observations at 12 weeks demonstrated regression toward baseline. However no definitive conclusions could be reached as unit personnel turnover closely paralleled reduction in adherence
- Tools:** Hand held computer units with data entry via a Graphic User Interface (GUI) allowed unobtrusive data collection in both the simulation laboratory and the clinical setting



Appendix E

Platelet Gel

**A RANDOMIZED PROSPECTIVE MULTI-CENTERED, INVESTIGATOR-BLINDED TRIAL OF
PLATELET RICH PLASMA (PRP) GEL VERSUS CONTROL FOR THE TREATMENT OF
DIABETIC NEUROTROPHIC LEG ULCERS**

INVESTIGATIONAL PLAN

Sponsor:

**United States Air Force administered by the
U.S. Army Medical Research Acquisition
Activity, Fort Detrick, Maryland**

University of Pittsburgh Medical Center (UPMC)

Date Approved:

Statement of Confidentiality and Investigator Signatures



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I hereby attest that I have read and understand the clinical protocol and agree to conduct the study as outlined. I will submit this protocol to the Ethics Committee, Institutional Review Board of my institution or to another appropriate committee and will not initiate this study without its prior approval.

 _____ Principal Investigator signature	<u>01/15/07</u> _____ Date signed	<u>David L. Steed, MD</u> _____ Printed name
 _____ Sub-Investigator signature	<u>01/15/07</u> _____ Date signed	<u>Thomas E. Serena, MD</u> _____ Printed name
_____ Sub-Investigator signature	_____ Date signed	_____ Printed name
_____ Sub-Investigator signature	_____ Date signed	_____ Printed name
_____ Sub-Investigator signature	_____ Date signed	_____ Printed name

Schedule of Required Study Procedures

Procedure	Patient Visit			
	Visit 1	Visit 2 ¹	Visit 3-13 ¹	Visits 14-16
Informed Consent	X			
Patient Characteristics	X			
Medical History	X			
Physical Exam	X	X	X	X
Vital Signs	X	X	X	
Body Mass Index	X			
Laboratory Tests ^{2,3}	X		X	
Ankle Brachial index	X	X	X	
Debridement of Wound	X	X	X	
Wound Characteristics, Measurement and Digital Photography	X	X	X	X
Wound Classification	X			
Wound Off-Loading		X	X	X
Adverse Events		X	X	X
WBC, GF Characterization, PRP GF Characterization		X		
PRPG and AT Production and Application ⁴		X	X	

1. Required assessments are performed weekly for 12 weeks or until wound is completely healed, whichever comes first.
2. Blood evaluations will include CBC, Serum chemistry, pre-albumin, platelet count, prothrombin time, partial thromboplastin time, serum pregnancy, Hbg-A1C, and urinalysis.
3. Growth factors characterization including; , PDGF-Platelet derived growth factor-AB, TGF-Beta 1 -Transforming growth factor - Beta 1, and VEGF-Vascular endothelial growth factor will be performed on week one (visit two) of treatment. Platelet activation will be measured with P-Selectin level at week one (visit two) of treatment.
4. Applies to subjects in the treatment arm only. PRPG is applied weekly for 12 weeks or until wound is completely healed, whichever comes first.

Volume of Whole Blood Required for Study-Related Activities (ml)

	Patient Visit				
	Visit 1	Visit 2	Visit 3-13	Visit 13	Visits 14-16
Laboratory Tests ⁵	20	10	0	20	0
Treatment Arm PRPG Production and Application	0	40	40	40	0
Total Whole Blood Drawn	20	40	40	60	0
ACD-A Anticoagulant Added	N/A	5	5	N/A	N/A
Total Anticoagulated Volume	N/A	40	40	N/A	N/A

5. Approximately 10 ml WB will be drawn for Growth Factor Characterization and P-selectin testing on visit 2, the first week of treatment from both treatment and control groups.

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A RANDOMIZED PROSPECTIVE MULTI-CENTERED, INVESTIGATOR-BLINDED TRIAL OF PLATELET RICH PLASMA (PRP) GEL VERSUS CONTROL FOR THE TREATMENT OF DIABETIC NEUROTROPHIC LEG ULCERS

I Introduction

Diabetic foot wounds are a significant health care problem in the United States, affecting 10-15 percent of 20 million patients with diabetes. Failure of these wounds to heal leads to amputation in 60,000-80,000 patients per year. The cost of care for a leg wound resulting in amputation is about \$70,000 per patient. At least half of these patients will lose the contra-lateral limb within five years.¹⁻³

Diabetic neurotrophic leg ulcers (DNLU) are a serious complication of diabetes. More than 20.8 million people in the US have diabetes, and 15% of them can be expected to develop a diabetic leg ulcer at some point in their lives. In general they include a combination of lower limb arterial insufficiency, lower limb diabetic neuropathy, and local trauma. About 20% of diabetic patients with leg ulcers will primarily have inadequate arterial blood flow, 50% will have diabetic neuropathy and 30% will be inflicted by both conditions. Inadequate arterial blood flow is usually treated by a variety of surgical techniques that will improve blood flow.

Diabetic neurotrophic leg ulcers present a more challenging problem in that there is no easy remedy. If arterial circulation is adequate for healing, then good care involves treatment of infection, off-loading, debridement, and proper dressing. There is no universally agreed upon cream, salve, or ointment for the treatment of DNLU. Successful treatment involves keeping the wound moist, often with saline or hydrogel. Other treatments include topical antibiotic creams and salves, hydro colloidal dressings, bio-occlusive dressings, enzymatic debriding agents and growth factors.

Recently the U.S. Food and Drug Administration approved several new treatments for patients with DNLU. These treatments represent two new treatment classes, growth factors and cell therapies, and are used in combination therapy with the above treatments. Even with the above products, success in treating DNLU is dismal. About 10-33% of the patients in the standard of care arm will heal in 12-20 weeks, whereas 30-50% of individuals receiving one of the new products will heal by 12-20 weeks of care.

Risk factors for developing DNLU are patient age, patient sex, duration of the wound, size of the wound, wound grade, number of wounds, prior care at the treatment center, and type of treatment center.

Platelets enter wounds to control hemorrhage. These platelets also bring growth factors, which are stored in their alpha granules. Growth factors are proteins that are present in small amounts yet exert a powerful influence over healing by acting as mitogens and chemoattractants.⁴ Growth factors can be extracted from the alpha granules of platelets, yielding a product known as a platelet releasate.⁵ Platelet releasates can be prepared from the patient's own platelets (an autologous product) or from pooled platelet donors (a homologous product).⁶ Platelet releasates have been tested in diabetic and venous stasis ulcers and a variety of other wounds, yet no homologous product has received FDA approval.⁷⁻¹² Autologous products, however, are frequently used and readily available under the name Procuren®.

A single growth factor can be made by recombinant DNA technology. Single growth factors, including Platelet-Derived Growth Factor (PDGF), Transforming Growth Factor-beta (TGF- β), Keratinocyte Growth Factor (KGF), Fibroblast Growth Factor (FGF), Insulin-like Growth Factor (IGF), Granulocyte Macrophage-Colony Stimulating Factor (GM-CSF), and Vascular Endothelial Growth Factor (VEGF) have been used in clinical trials of wound healing. As yet, only PDGF, also known as becaplermin or Regranex, is approved of use in the United States. Despite proof of benefit from PGDF in several randomized prospective double blind trials and widespread use of platelet releasate, the amputation rate remains the same.

Platelet rich plasma (PRP) gel can be prepared from several ounces of blood, if the platelet count and hemoglobin are normal. PRP gel contains at least 19 growth factors. In theory PRP gel offers greater benefit to healing than an isolated growth factor since it more closely mimics natural healing. Growth factor levels in wound fluids increase during the course of healing, and over time the spectrum of growth factors changes. Messenger RNA for growth factors is upregulated in the wound. It makes sense; therefore, that PRP gel harvested from a patient and reapplied as an autologous preparation would be of benefit in healing and offer an approach consistent with nature.

PRP gel (PRPG) can be made by adding autologous thrombin and calcium to a platelet pellet spun from a patient's own blood. The gel can be applied to a wound and left in place for up to one week. This autologous preparation offers minimal risk to the patient.

II Regulatory Compliance

This clinical pilot study, which will be conducted according to this protocol, is designed to meet the requirements of and will be conducted in accordance with the following:

- U.S. Code of Federal Regulations (CFR) 21 Part 812 "Investigational Device Exemptions", Part 50 "Protection of Human Subjects", & Part 56 "Institutional Review Boards"
- Declaration of Helsinki, October 2000

III Purpose

This clinical pilot study will be conducted to assess and evaluate the safety and efficacy of the use of autologous Platelet Rich Plasma Gel for the treatment of chronic (greater than 8 weeks in duration) diabetic neurotrophic leg ulcers.

An extract of activated platelets that is rich in platelet derived growth factors has been shown to enhance the healing of cutaneous ulcers and was previously commercialized under the name Procuren[®]. In addition, platelet derived growth factors as an isolated cytokine have been shown to enhance wound healing in several animal studies and non-healing wounds in humans.

IV Study Objectives

A. Primary Objective

The primary objective of this pilot study is to evaluate the safety and efficacy of PRP Gel and autologous thrombin in healing chronic diabetic neurotrophic leg ulcers as compared with standard care.

B. Secondary Objectives

- To compare percent reduction in wound area between treatment groups, within a stratified population, at 12 weeks.
- To compare time to wound closure (≤ 12 weeks) between treatment groups, within a stratified population.
- To compare wound recurrence rates between treatment groups, within a stratified population, at any time between the end of treatment and the 3-month follow-up visit.
- To compare incidence of infection of the study wound between treatment groups, within a stratified population, during the 12-week treatment period.
- To compare the incidence of safety-related events between treatment groups, within a stratified population, during the 12-week treatment period.

C. Data Endpoints

Primary

- Wound closure at 12-weeks post-treatment initiation.

Secondary

- Time to wound closure (wound closure rate) (when ≤ 12 weeks).
- Infection
- Wound recurrence at any time between end of treatment and the 3-month follow-up visit.
- Wound increase in size $\geq 30\%$.
- Wound enlarges on two consecutive visits
- Co-morbidities.
- Patient compliance with treatment regimen (yes/no outcome) between completion of study treatment and 3 month follow-up.
- Adverse events
- Develops an occurrence of an additional wound within 3 cm of the study wound
- Study extremity requires revascularization or amputation
- Patient no longer wish to participate in the study
- PRPG cannot be applied to the study wound for 2 consecutive weeks
- At the discretion of the physician for health reasons associated or not associated with the study

V Device Description

One system, the FDA approved COBE Angel Whole Blood Separation System, will be used by all clinics for this study. The COBE Angel Whole Blood Separation System consists of a blood centrifugation device and two associated disposables: the Processing Set and the Whole Blood Access Kit. The system is designed to be used at the patient's point-of-care to sequester platelet rich plasma, platelet poor plasma and concentrated red blood cells from a sample of whole blood. These products are currently on the US market and will not be modified to support this study (reference 510(k)'s K042473 and BK050033).

The Processing Set contains a variable volume separation chamber that is capable of separating from 40 to 180 ml of ACD anti-coagulated autologous whole blood into red blood cells, platelet poor plasma, and platelet rich plasma. The Processing Set is provided sterile and is for single use only. Each disposable set can be used for one processing cycle. The Processing Set consists of the variable volume separation chamber as well as tubing, a platelet sensor/valve assembly, and a three-compartment reservoir bag to hold the whole blood, red blood cells, and platelet poor plasma. A luer lock syringe is provided to collect the platelet rich plasma.

The Whole Blood Access Kit is a convenience kit that contains pre-packaged, pre-sterilized devices for obtaining whole blood to be separated using the Angel System. The individual components are placed into a single box for the convenience of the user and are not re-packaged, re-sterilized, or otherwise altered. The kit contains an IV Site Kit for preparing the venipuncture site, one skin prep single swab (povidone iodine), one 17-gauge fistula needle for accessing the venipuncture site, one vial of ACD for use as an anticoagulant during blood collection, two 18-gauge needle for accessing the ACD from the vial, and two 60-ml syringes for collecting the blood. All components of the kit are labeled for single use only and are not to be re-used or re-sterilized by the user.

The Angel system performs blood component separation and will be used in this study to produce the autologous Platelet Rich Plasma Gel. "Autologous" relates to the use of products or components from the same individual. The Investigator will produce the Platelet Rich Plasma Gel at the point of care using separated blood products from the patient to be treated. The gel will be made from the combination of the patient's autologous platelet-rich-plasma (PRP), autologous thrombin, and 10% calcium chloride solution (USP). A commercially available FDA approved applicator will be used to mix the PRP, thrombin, and calcium chloride.

Because topical bovine thrombin has been linked to the development of antithrombin antibodies and resulting coagulopathies^{18,19} autologous thrombin will be used instead of bovine thrombin. It will be produced using an active autologous thrombin processing kit (activAT) manufactured by Cobe Cardiovascular, a Sorin Group Company. Pre-trial assessment of autologous thrombin potency will be documented. (reference documentation) During the trial, observation of firm gel and measurement of the selected growth factors (PDGF-Platelet derived growth factor-AB, TGF-Beta1-Transforming growth factor -Beta 1, VEGF-Vascular endothelial growth factor, and P-selectin) will be used as an indication of adequate activation.

VI Protocol

A. Study Design

This is a randomized, prospective, multi-centered, investigator blinded pilot study of platelet rich plasma gel versus control for the treatment of diabetic neurotrophic leg ulcers of 8 weeks or greater.

B. Anticipated Enrollment Period:

The total time from submission to the first Investigational Review Board (IRB) to completion of follow-up visits of last patient enrolled is projected to be 36 months

- **Timeline:**
 - 6-9 Months: Because this is a significant risk, multi-center, human trial involving Department of Defense Funding we will be submitting this protocol to two Investigational Review Boards (IRB); University of Pittsburgh Medical Center and Wilford-Hall Medical Center. This protocol must also receive second level approval from the office of the Surgeon General Office of the United States Air Force. In addition, we must first receive an Investigational Device Exemption (IDE) from the FDA. Since the FDA/IDE process takes 1-3 months and each IRB has a unique template to follow and both IRBs must approve before patients are enrolled we have allowed 6-9 months before the first patient is enrolled.
- 9-27 Months: During this phase we will begin recruitment of patients. The projected patient enrollment distribution is as follows; UPMC/Shadyside 25 total or ~2/month, UPMC North (Horizon, Shenango, and Greenville) 25 or ~2/month, and Wilford Hall 10 or ~1/month. Upon commencing enrollment we anticipate having all patients enrolled within 12 months, allowing for a three-month follow-up for a total trial period of 15 months. If projected enrollment target is not met we will expand recruitment efforts. If we continue to fall short we will contact the respective IRBs requesting an extension of recruitment period.
- 27-36 Months: Completion of records, collation of data, statistical analysis, preparation of manuscript, and submission to peer review journal for publication.
- **Anticipated Study Completion:** Three months after last patient completes treatment.

C. Investigational Site Participation

This pilot study will be conducted at these five investigational sites. All sites will follow the same protocol. Each site will seek approval from the IRB affiliated with its facility. The two affiliated IRBs are University of Pittsburgh Medical Center and Wilford Hall Hospital. In addition, the study will require second level DoD approval from the Surgeon General Office of the United States Air Force.

Current sites are:

- UPMC Shadyside Wound Healing and Limb Preservation Clinic
- UPMC Horizon Greenville Center for Wound Treatment
- UPMC Horizon Shenango Valley Center for Wound Treatment

- UPMC Northwest Wound Clinic
- Wilford-Hall Medical Center Diabetes Clinic

D. Patient Population

This study will screen up to 100 patients and enroll up to 70 patients with diabetic neurotrophic leg ulcers; 30 patients per treatment arm, plus 10 additional patients due to an anticipated 10% withdraw rate and 7% withdraw rate as a result of infection. Patients will be randomized on a 1:1 basis to either standard treatment (standard of care group) or standard treatment with the replacement of Hydrogel with PRPG (treatment group).

Control Group				
Population Range	Number of Participants	GF Testing (5 GFs)	PRP GF Testing (5 GFs)	Autologous Thrombin
18-45	10	N/A	N/A	N/A
46-60	10	N/A	N/A	N/A
61-85	10	N/A	N/A	N/A
Total	30			

Treatment Group				
Population Range	Number of Participants	GF Testing (5 GFs)	PRP GF Testing (5 GFs)	Autologous Thrombin
18-45	10	1 @ wk 2	1 @ wk 2	1 @ wks 2-13
46-60	10	1 @ wk 2	1 @ wk 2	1 @ wks 2-13
61-85	10	1 @ wk 2	1 @ wk 2	1 @ wks 2-13
Total	30			

E. Treatment Summary

“Standard Treatment” for the Standard of Care Group will consist of:

- Weekly visits
- Debridement of wound to necrosis free state, using sharp instrument
- Application of Hydrogel
- Coverage of wound with Allevyn

Therapy for the “Treatment Group” will consist of:

- Standard treatment as described above, except that Platelet Rich Plasma Gel will be topically applied to the wound bed in place of Hydrogel.
- Phlebotomy will be performed in order to produce the Platelet Rich Plasma Gel and Autologous Thrombin

F. Patient Selection Criteria

1. Inclusion criteria

Patients must meet all the following inclusion criteria to be eligible for enrollment in the study:

- a. The patient must be 18 - 85 years of age
- b. Wound shows no clinical signs of infection
- c. No sign of Osteomyelitis
- d. Ulcers must be 0.5 to 12 cm² in area after debridement
- e. Wound debrided to necrosis free state
- f. HGB A-1C \leq 10%
- g. The patient must have diabetes and neuropathy as determined by insensitivity to a 5.07 Semmes-Weinstein monofilament on the toes, metatarsal region or dorsum of the foot
- h. The patient must have full-thickness ulcers below the malleolous with no exposed bone, tendon or open joint after debridement
- i. Ulcers must be present for at least eight weeks without healing
- j. The patient must have adequate arterial circulation to the foot as documented by ankle/brachial index (ABI) greater 0.7 but less than 1.3
- k. The patient must be able to understand the study protocol and provide written informed consent
- l. If patient is a woman of child-bearing age, the patient must not be pregnant and must use a method to prevent pregnancy during the study period
- m. Wound has not been present for longer than two years
- n. Wound does not decrease in size by 30% during the observation time
- o. Wound does not increase in size by 30% or enlarges by 30% on two consecutive visits
- p. Patient does not require systemic antibiotic therapy
- q. Patients with wounds that can be completely off-loaded
- r. Patients who are not pregnant and/or lactating
- s. Patients who are not in steroids, cytotoxic agents, or radiation therapy
- t. Non-Immunocompromised patients
- u. Patients with serum creatinine \leq 2.5 mg/dl or patients on dialysis
- v. Patient with liver function studies \leq twice the upper limit of normal
- w. Patients that have not had cancer within the past five years.
- x. Patients not taking heparin, warfarin, clopidogrel, or ticlopidine
- y. Patients with serum albumin $>$ 2 g/dl
- z. Patients with known hematocrit $>$ 32%
- aa. Patients with a platelet count $>$ 100,000/mm³
- bb. Patients without symptomatic congestive heart failure
- cc. Patients without connective tissue disorders or vasculitis
- dd. Patients willing and able to comply with study requirements
- ee. Patients who have not participated in another experimental drug or device trial within the past 30 days
- ff. Patients without known ethanol sensitivity
- gg. Patients with a Wagner Wound Classification Grade 1 or 2
- hh. Patients with multiple wounds must have a single wound $>$ 3cm away from the nearest wound

- ii. Patients with a wound that does not contain Charcot areas

2. Exclusion criteria

The presence of any of the following will exclude a patient from study enrollment:

- a. The patient younger than 18 years of age
- b. Wound shows clinical signs of infection
- c. Osteomyelitis
- d. Ulcers < 0.5 and $> 12 \text{ cm}^2$ in area after debridement
- e. Wound debrided is unable to produce necrosis free state
- f. HGB A-1C $> 10\%$
- g. The patient must have diabetes and neuropathy as determined by insensitivity to a 5.07 Semmes-Weinstein monofilament on the toes, metatarsal region or dorsum of the foot
- h. The patient does not have full-thickness ulcers below the malleolous with no exposed bone, tendon or open joint after debridement
- i. Ulcers have not been present for at least eight weeks without healing
- j. The patient does not have adequate arterial circulation to the foot as documented by ankle/brachial index (ABI) greater 0.7 but less than 1.3
- k. The patient is unable to understand the study protocol and provide written informed consent
- l. If patient is a woman of child-bearing age, the patient is pregnant and is unable to use a method to prevent pregnancy during the study period
- m. Exposed bone at the base of the wound
- n. Wound present for longer than two years
- o. Clinical signs of infection
- p. Wound decreases in size by 30% during the observation time
- q. Wound increases in size by 30% or enlarges by 30% on two consecutive visits
- r. Patient requiring systemic antibiotic therapy
- s. Patients with wounds that cannot be completely off-loaded
- t. Patients who are pregnant and/or lactating
- u. Patients who are in steroids, cytotoxic agents, or radiation therapy
- v. Immunocompromised patients
- w. Patients with serum creatinine $> 2.5 \text{ mg/dl}$ or patients on dialysis
- x. Patient with liver function studies $>$ twice the upper limit of normal
- y. Patients with cancer within the past five years
- z. Patients taking heparin, warfarin, clopidogrel, or ticlopidine
- aa. Patients with serum albumin $< 2 \text{ g/dl}$
- bb. Patients with known hematocrit $< 32\%$
- cc. Patients with a platelet count $< 100,000/\text{mm}^3$
- dd. Patients with symptomatic congestive heart failure
- ee. Patients with connective tissue disorders or vasculitis

- ff. Patients unwilling or unable to comply with study requirements
- gg. Patients who have participated in another experimental drug or device trial within the past 30 days
- hh. Patients with known ethanol sensitivity
- ii. Patients with a Wagner Wound Classification Grade 3, 4, and 5
- jj. Patients with multiple wounds do not have a single wound > 3cm away from the nearest wound
- kk. Patients with a wound that contains Charcot areas

G. Patient Randomization

A patient treatment randomization scheme will be computer generated at UPMC. UPMC/Shadyside will conduct the centralized randomization process. All patients, regardless of facility, will be randomized in a 1:1 ratio into the two arms, experimental and control. A blinded neutral observer, from UPMC/Shadyside, will keep the centralized randomization list. As patients are entered into the study, regardless of the facility, they will be consecutively assigned a study number from the list of subjects who are to receive PRP gel and standard care or standard care alone and based on that number assigned to one of the two treatment groups. The investigator will be blinded as to the treatment group of each patient. Blood will be drawn on patients in the treatment group after the investigator has examined the patient. A bandage will be applied to all patients before leaving the clinic. In the event of an emergency in which the patient's treatment group must be known in order to treat an adverse event or other medical problem, un-blinding may occur. This must be documented in the perceived un-blinding event log and reported to the medical monitor and the Investigator within 48 hours.

Patients, regardless of their facility, will be centrally randomized, at the UPMC/Shadyside facility, to either standard treatment (standard of care group) or standard treatment with the replacement of Hydrogel with PRPG (treatment group). Randomization will take place at the time of patient enrollment, after the following:

- Patient has given written informed consent
- All screening assessments have been completed
- The patient has met all eligibility criteria

H. Study Evaluation and Procedures

1. Informed Consent

The Investigator must inform the patient of the nature of the research, of the risks and potential adverse effects of the PRP Gel, the possible benefits of its use, and alternative modes of treatment. The Investigator is encouraged to use the study-specific **Informed Consent Form** (Appendix B). If an investigating center chooses to use an alternatively worded written consent document, the Institutional Review Board (IRB) at that center must also approve the consent.

Prior to participation in the study, the informed consent document will be reviewed with each patient who meets the eligibility criteria. If the patient chooses to participate, the patient will sign and date the study-specific informed consent document and will initial each page, if indicated. The Investigator or the person who

conducts the informed consent discussion as well as a witness may also sign and date the document. The original signed informed consent is to be kept on file with the patient's study records and a signed copy is to be given to the patient.

2. Treatment Protocol

- For patients with multiple wounds, the treating physician will select only one wound for randomized treatment. The selection will be based on the wound meeting the size criterion of this study, ease of access, regular boundaries for more consistent measurement determination, and the selected wound must be at least three centimeters (3 cm) away from the nearest wound.
- Patients will receive standard group or treatment group wound care for 12 weeks unless the investigator observes one of the following attributes of the study wound: infection, increase in size by 30%, enlarges by 30% on two consecutive visits, or completely healed.

All patients will be evaluated in the wound clinic for two weeks prior to treatment in the study. Patients will then be seen in the clinic weekly until the patient has received 12 weeks of care, or until the investigator observes one of the study secondary data end points. At each weekly visit, wounds will be evaluated. The patient's medical status will be recorded, and adverse events will be noted and recorded. Wounds will be debrided as needed. The investigator will then leave the room and the research coordinator/study nurse/perfusionist will perform the following steps: measure and document the current wound size, capture digital photographs of the wound, apply the appropriate gel based on the study group, and dress the wound. The same person will perform the measurements and digital photographs for all of the patients' study wounds. Complete wound healing will be defined as a closed wound with mature epithelium, free of infection with no dressing required. Complete healing will be the judgment of the principal investigator. Patients who heal or have completed 12 weeks of care will then be seen monthly for three months.

3. Data Collection

Data collection for this study will use a Case Report Form (CRF) method. The Investigator is responsible for legibly recording the required study information into patient charts as the source documents for this study and for verifying that all entries in the source documents are complete and correct by signing and dating each chart page. The site is responsible for accurately entering the data onto study-specific CRFs.

a. Baseline Procedures: Visit 1 (Screening Visit)

To enter the trial, the patient must have a freshly surgically debrided ulcer. Baseline evaluations to be collected at this visit will be recorded on the Pre-Study Enrollment CRF. These data will include:

- Patient characteristics (date of birth, sex, height, weight)
- Medical history (including study ulcer duration) will be collected from the patient on the enrollment CRF. An attempt will be made to retrieve the patient's medical history from their primary care physician. If the patient's

medical history is unavailable, at the time of the study, the patient's oral account of their medical history will be documented for the status and duration of the ulcer

- Physical examination (including examination of the affected extremity)
- Vital Signs
- Body mass index
- The patient will be phlebotomized to harvest the patient's whole blood.
- Laboratory tests (including CBC, Serum chemistry, pre-albumin, platelet count, prothrombin time, partial thromboplastin time, serum pregnancy, Hbg-A1C, and urinalysis)
- Ankle brachial index, TCPO2, or toe systolic blood pressure.
- Debridement of the chosen study wound to necrosis free state (note: debridement of the chosen study must remove all unhealthy tissue, debris, and excess exudates, leaving a clean moist and viable wound bed).
- Baseline measurement of the area of the chosen study wound using the Visitrak system and digital photographs (taken at 6 in (15 cm) and 18 in (46 cm) from wound surface). (See Protocols 1 and 2)
- Wound Classification

b. Weekly Assessment Regimen: Visits 2-13

All patients will receive standard care. (Refer to SOP #7)

Information collected from these visits will be recorded on the Weekly Evaluation **CRF**. These data will include:

- Physical examination of the affected extremity
- Evaluation of the treatment wound with regard to the inclusion and exclusion criteria to ensure that the treatment wound still qualifies for participation in the study
- Vital signs
- Wound characteristics (e.g. erythema, amount and color of drainage)
- Debridement of the study wound to necrosis free state (note: debridement must remove all unhealthy tissue, debris, and excess exudates, leaving a clean, moist and viable wound bed). Documentation of whether debridement was performed and type (sharp instrument or other).
- Measurement of the wound area using the Visitrak system and digital photographs will be collected by the research coordinator/study nurse (taken at 6 in (15 cm) and 18 in (46 cm) from wound surface). The same person will perform the measurement and digital photographs for all patients' study wounds. (Refer to SOP #1 and #2)
- Ankle brachial index
- The patient will be phlebotomized to harvest the patient's whole blood.
- Growth Factor Characterization will only be performed using the patient's whole blood obtain from all patients in the treatment arm. (PDGF-Platelet derived growth factor-AB, TGF-Beta1-Transforming growth factor -Beta 1, VEGF-Vascular endothelial growth factor, and P-selectin) The whole blood harvested from all patients in the control arm will be used for standard testing only.
- Production and application of PRPG and autologous thrombin for all patients in the treatment arm.

- Growth Factor Characterization will be performed on the PRPG and autologous thrombin for all patients in the treatment arm (PDGF-Platelet derived growth factor-AB, TGF-Beta1-Transforming growth factor -Beta 1, VEGF-Vascular endothelial growth factor, and P-selectin).
- Wound Care (Refer to SOP #6)
- Wound dressing changes will be performed weekly. For patients in the standard of care group, these dressing changes will consist of application of Hydrogel agent to the wound bed, coverage of the wound with Allevyn, and application of multi layer gauze wrap. Patients in the Treatment Group will receive the same dressing changes, except the PRPG will be applied to the wound bed instead of Hydrogel agent. The PRPG will be applied with a standard spray applicator tip. An amount sufficient to completely cover the exposed tissue 2-4 mm in depth will be applied. Specific details on PRPG production are found on Appendix A.
- Under normal circumstances the patient is prohibited from removing the dressing between office visits. Reasonable care to avoid wetting and premature removal of the dressing will be instructed to the patient. However, if the dressing becomes saturated with drainage between visits, or if the dressing were to fall off or become dislodged, the patient may flush the wound with water and apply a hydrogel dressing. The patient should always change the dressing seven days after an office visit using hydrogel unless the patient has a study visit that day. The patient should report this event to the PI within 24 hours.
- Verify wound off-loading

All complications will be reported in detail on an **Adverse Event CRF**.

c. Post Treatment Study: Visits 14-16

Upon healing or completion of 12 weeks of treatment, patients will enter the post-treatment phase and will be seen monthly for three months. At each monthly visit, the ulcer site will be photographed and measured by the research coordinator/research nurse. The same person will perform the measurement and digital photographs for all of the patients' study wounds. Persistent healing or recurrent ulceration documented by the Investigator.

The follow-up data listed below will be collected and recorded on the Monthly Follow Up Visit CRF. These data will include:

- Status of wound at time of visit.
- Patient compliance with off-loading and wound care.
- Wound size.
- Digital photographs of wound (at 6 in (15 cm) and 18 in (46 cm)) taken and brought for physician review.

All adverse events must be documented on the **Adverse Event CRF**.

4. End of Treatment

End of treatment will occur when at least one of the following events occur with the study wound:

- Completely healed
- Participation in the study for the entire 12 weeks
- Infection
- Wound increase in size $\geq 30\%$.
- Wound enlarges on two consecutive visits
- Co-morbidities
- Adverse events
- Develops an occurrence of an additional wound within 3 cm of the study wound
- Study extremity requires revascularization or amputation

End of treatment will occur if one of the following events occurs:

- Patient no longer wish to participate in the study
- PRPG cannot be applied to the study wound for 2 consecutive weeks
- At the discretion of the physician for health reasons associated or not associated with the study

If the wound completely heals during the treatment period (≤ 12 weeks), treatment will be discontinued with the exception of strict off-loading of wound, digital photography, and three subsequent monthly visits

After 12 weeks of treatment, or when the ulcer has healed, wounds will be photographed; blood will be drawn for complete blood count, serum chemistry, and serum pregnancy (if applicable). Urinalysis will be performed. Complete physical examination will be performed. Adverse events will be noted. The patient will be fit with diabetic shoes with insert. The patient will be instructed on care of the diabetic foot.

5. Treatment Failures

If the study wound experiences the following characteristics, the patient will be considered a treatment failure and will end participation in the study and resume normal treatment regimen. No additional follow up visits required. For statistical purposes, these patients will be considered in the intent to treat population.

- Time to wound closure > 12 weeks
- Infection
- Wound recurrence at any time between end of treatment and the 3-month follow-up visit.
- Wound increase in size $\geq 30\%$.
- Wound enlarges on two consecutive visits
- Co-morbidities
- Develops an occurrence of an additional wound within 3 cm of the study wound

- Study extremity requires revascularization or amputation
- Patient no longer wish to participate in the study
- PRPG cannot be applied to the study wound for 2 consecutive weeks
- At the discretion of the physician for health reasons associated or not associated with the study

6. Follow-Up

Patients with a healed wound at or before 12 weeks will be seen for three monthly follow-up appointments after completion of the study treatment to determine wound status at that time. Patients will be instructed to call investigational site personnel if the wound recurs prior to any of the monthly visits

7. Failed Phlebotomy

If application of the Platelet Rich Plasma Gel cannot occur at a weekly visit due to problems phlebotomizing the patient or producing the PRPG, the problem will be noted on the associated weekly case report form. All other assessments/treatments will be done that week with the exception of applying the PRPG (the patient will not receive Bactroban or another anti-microbial ointment in place of the PRPG). If PRPG application does not occur for two consecutive weeks, the patient will be withdrawn from the study. All patients withdrawn from the study as a result of a failed phlebotomy or failure to produce PRPG will be included in the statistical intent to treat population.

8. Study Procedures

a. Wound Photography

Digital photographs of the study wound will be taken at the pre-study evaluation, at each weekly visit, and monthly at the follow-up visit by the research coordinator/research nurse. The investigator will not participate in the acquisition of the digital photographs of the study wound. Photographs will be taken using a 4.0 megapixel (or higher) digital camera, and will be taken looking straight down on the study wound. A measurement device (sterile ruler or equivalent) must be included in the photograph to allow quantification of the wound area. Two photographs of the wound will be taken, one at 6 in (15 cm) and one at 18 in (46 cm) from the surface of the wound. Each photograph will include the date the photographs were taken, the study number, and the subject study identification number. Photographs from each session will be stored on a diskette, identified by the date the photographs were taken, the study number, and the subject study identification number. Each diskette will contain only the photographs from a single subject and a single weekly visit.

b. Ulcer Classification

Diabetic Neurotrophic leg ulcers are chronic wounds associated with long-standing diabetes of the lower extremities. During this study, chronic diabetes disease of the lower extremities will be categorized using the Wagner

classification system: clinical manifestations, etiologic factors, anatomic involvement, and pathophysiologic features (reference Appendix D). A diabetic neurotropic ulcer must meet the criteria for grade 1 or grade 2 in the Wagner Classification¹⁶⁻¹⁷ scale to qualify for inclusion in the study.

c. Wound Healing (Closure)

Complete wound healing (closure) is defined as full epithelialization of the wound and no drainage from the site.

9. Management of Subjects Who Develop Infection, Osteomyelitis, or Dermatitis During Trial Participation

Infection of the study wound, identified either through clinical observation (erythema, edema, induration, purulent drainage, foul odor, warmth at the wound site, or fever >37.8 degrees C, tenderness, and increasing pain at the wound site) or by a quantitative culture results of >100,000 colonies/gram requires systemic antibiotics and appropriate local management as determined by the Investigator until the infection is resolved. If the study wound (or a non-study wound on the same extremity) becomes infected, study treatment will be discontinued to allow the infection to be treated. Once the infection has resolved, the subject will not be permitted to return to his/her treatment group. At this point, the treatment will be discontinued and considered a study failure. The patient will then resume a normal treatment regimen. All patients withdrawn from the study as a result of an infection will be included in the statistical intent to treat population.

The presence of exposed bone will be presumptive evidence of Osteomyelitis. If this occurs, treatment will be interrupted and the exposed bone treated by the investigator as per their best judgment. Once the Osteomyelitis has been identified, the treatment will be discontinued and considered a study failure. The patient will then resume a normal treatment regimen to resolve the Osteomyelitis. All patients withdrawn from the study as a result of an Osteomyelitis will be included in the statistical intent to treat population.

Dermatitis at the study wound site will require determination of the cause and treatment as deemed appropriate by the wound care physician. If dermatitis is identified, the treatment will be discontinued and considered a study failure. The patient will then resume a normal treatment regimen to resolve the dermatitis. All patients withdrawn from the study as a result of dermatitis will be included in the statistical intent to treat population.

I. Adverse Events

An **adverse event** is **any untoward medical occurrence**, whether anticipated or unanticipated, in any patient during the course of the study. The Principal Investigator is required to **report all untoward medical events**. All adverse events will be reported on the **Adverse Event CRF** and may or may not be device related. Adverse events that are associated with the use of Platelet Rich Plasma Gel are cited in the **Risks** (Section VII).

1. Adverse Events

A **serious adverse event** is defined as any untoward medical event that

- results in a death
- is life-threatening (real risk of dying at the time of the event)
- requires hospitalization (initial or prolonged)
- results in disability (significant, persistent or permanent)
- requires intervention to prevent permanent impairment or damage

A. Infection. The most common adverse event anticipated is infection. It is expected that the infection rate will be similar among groups. Wound culture and sensitivity must be performed. Infection is defined as three of the five clinical signs: erythema, edema or induration, warmth at the wound site or fever > 37.8 degrees C, tenderness, and increasing pain at the wound site. The presence of exposed bone will be presumptive evidence of osteomyelitis. If this occurs, treatment will be discontinued and the exposed bone treated by the investigator as per their best judgment. If clinical infection develops during the course of treatment, the patient will be dropped from the study and not allowed to re-enter. They will not resume treatment once the infection is cleared. All patients withdrawn from the study as a result of an infection will be included in the statistical intent to treat population.

B. Wound size changes. If the wound decreased by 30% during the observation time, the patient will be excluded. If the wound worsen by 30% or enlarges on two consecutive visits, the patient will be withdrawn from the study and will be considered a study failure. All patients withdrawn from the study as a result of an the defined wound size changes will be included in the statistical intent to treat population

C. Infrequent side effects occur in 1-10%, or 1-10 out of 100 people. Itching, hives, nausea, and vomiting may be expected in 1-2% of the individuals that receive Platelet Gel. These side effects are usually mild in severity.

D. You may experience bruising and soreness at the site where blood is drawn. There is also a slight possibility of infection at the site where the blood is drawn.

E. Studies evaluating the capability of the medication under investigation to produce birth defects in an unborn child have not been completed/conducted.

F. As a FEMALE OF CHILDBEARING POTENTIAL wishing to volunteer for this project, you must understand that the Platelet Gel might be harmful to (1) an unborn child if you are pregnant, or become pregnant; or (2) an infant if you are breastfeeding. Therefore, you may not be pregnant and will take a pregnancy test before and after you participate in this study. You must also agree to take precautions to prevent pregnancy during the course of this study due to the possible severe harm the drug/procedure may cause your unborn child. The only completely reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap,

birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. Also, you may not breast-feed and participate in this study.

- G. If you become pregnant or feel you might be pregnant, contact your provider and the study investigator listed in the voluntary participation section.
- H. As a MALE who wishes to volunteer for this project, you must understand that this drug/procedure might be harmful to an unborn child if your partner(s) should become pregnant. Therefore, you must agree to ensure that precautions are taken to prevent pregnancy from occurring during the course of this study due to the possible severe harm the drug/procedure may cause the unborn child.

Investigator Adverse Event Reporting

The safety of all patients enrolled in this clinical trial will be monitored throughout the study. All serious adverse events occurring with any patient enrolled in this study will be assessed by the Principal Investigator and reported within 24 hours with a written report within 48 hours. A report will also be provided to the IRB(s) and the University of Pittsburgh Diabetes Institute within 10 working days after the Investigator first becomes aware of the event using the Adverse Event Report case report form provided. The nature and causes of the problem will be reported and any treatment that is administered due to the unanticipated effect will be described in detail.

It is the responsibility of the Principal Investigator to conduct an evaluation of each adverse event and, with respect to applicable regulations, to determine if it is an unanticipated adverse device effect. If the event is determined to be an unanticipated adverse device effect, all participating investigators, the FDA and all reviewing Institutional Review Boards will be notified. The Investigator may stop you the patient from taking part in the study at any time if the Investigator believe it is in the best interest of the patient; if the rules are not followed; or if the study is stopped.

J. Data Safety Monitoring Board

An Institutional Data and Safety Monitoring Board (IDSMB) will be created to review this study. The initial responsibility of the IDSMB will be to approve the initiation of this clinical trial. After this approval and at periodic intervals (to be determined by the subcommittee) during the course of the trial, the IDSMB responsibilities are to:

1. Review the research protocol, informed consent documents and plans for data and safety monitoring;
2. Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect study outcome;
3. Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
4. Review clinical centers performance, make recommendations and assist in the resolution of problems reported by the PI;
5. Protect the safety of the study participants;

6. Report on the safety and progress of the trial;
7. Make recommendations to the PI, and if required, to the FDA concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
8. If needed, conduct interim analysis to include evaluation of efficacy in accordance with stopping rules which are clearly defined in advance of data analysis and have the approval of the IDSMB;
9. Ensure the confidentiality of the trial data and the results of monitoring;
10. Assist the PI by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

The IDSMB will include experts in chronic wound patients, diabetic foot ulcers, clinical trials methodology, and biostatistics. Members will consist of persons affiliated with the University of Pittsburgh, the University of Pittsburgh Medical Center (UPMC) and Wilford Hall Medical Center (USAF), but independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. Written documentation attesting to absence of conflict of interest will be required.

The University of Pittsburgh Office of Clinical Research, Health Sciences will provide the logistical management and support of the IDSMB. A safety officer (chairperson) will be identified at the first meeting. This person will be the contact person for serious adverse event reporting. Procedures for this will be discussed at the first meeting.

The first meeting will take place before initiation of the trial to discuss the protocol, approve the commencement of the trial, and to establish guidelines to monitor the study. The follow-up meeting frequency of the IDSMB will be determined during the first meeting. An emergency meeting of the IDSMB will be called at any time by the Chairperson should questions of patient safety arise. The principal investigator, co-investigators, and/or other study team members from each performance will be present for each meeting.

K. Patient Withdrawal or Discontinuation (Stopping Rules)

Subjects unable to comply with the requirements of the study such as the following will be withdrawn from the study:

- Treatment with immunosuppressive
- Cytotoxic
- Corticosteroids
- Anticoagulant agents such as Heparin, Plavix or Coumadin
- Needing radiation or chemotherapy
- Those who develop infection or dermatitis

If the study wound experiences the following characteristics, the patient will be considered a treatment failure and will end participation in the study and resume normal treatment regimen. No additional follow up visits required. For statistical purposes, these patients will be considered in the intent to treat population.

- Time to wound closure > 12 weeks
- Develops an infection that must be treated with antibiotics

- Wound recurrence at any time between end of treatment and the 3-month follow-up visit.
- Wound increase in size $\geq 30\%$.
- Wound enlarges on two consecutive visits
- Co-morbidities
- Develops an occurrence of an additional wound within 3 cm of the study wound
- Study extremity requires revascularization or amputation

If one of the following events occur with the patient, the patient will also be considered a treatment failure and will end participation in the study and resume normal treatment regimen. No additional follow up visits required. For statistical purposes, these patients will be considered in the intent to treat population.

- Patient no longer wish to participate in the study
- PRPG cannot be applied to the study wound for 2 consecutive weeks
- At the discretion of the physician for health reasons associated or not associated with the study
- Adverse Event

Patients who discontinue study participation because of adverse experiences will be treated and followed according to established medical practice, and the outcome of such treatment will be recorded on the **Adverse Event CRF**.

L. Site Discontinuation

The Investigator has the right to discontinue enrollment and remove all treatment materials from the study site for the following reasons:

1. It becomes apparent that patient enrollment is unsatisfactory as to quality (violations of inclusion/exclusion criteria) and/or enrollment rate;
2. The completion of the CRFs is inaccurate, incomplete and/or considerably delinquent.
3. The Investigator believes that it is in the best interest of the patients, when the study rules are not followed appropriately, that the enrollment and or the study be stopped.

M. Data Analysis and Statistical Methods

All case report forms will be returned to the research coordinator/research nurse for entry into a study database. The data will be checked for consistency and completeness.

1. Sample Size

This study is designed to compare the incidence of wound closure between two treatment groups: standard therapy (standard of care) and standard therapy with the substitution of Platelet Rich Plasma Gel for the Hydrogel (treatment). The primary outcome is incidence of wound closure during the 12-week treatment period.

Published studies for diabetic neurotrophic leg ulcers have shown that standard care treatment results in wound closure rates of approximately 10-33%. It is hypothesized that the experimental treatment will improve on the stand care wound closure percentage. A sample size of 30 patients per group should provided the investigator with a significant scientific statistical analysis to support the hypothesis. To accommodate the potential of a 17% withdrawal and infection rate, a sample size of 35 patients per treatment group (a total potential enrollment of 70 patients) is planned.

2. Statistical Methods

Descriptive statistics will be used to summarize treatment group comparability for demographic variables, overall and by investigational site. Summaries will also be provided for primary and secondary outcomes, as well as adverse event experiences.

The primary outcome of incidence of wound closure at 12 weeks post-treatment initiation will be analyzed using a chi-square test for contingency tables. To assess the potential influence of co-factors such as investigational site effects, logistic regression will be used.

Secondary outcomes consisting of time-to-event data will be analyzed by Kaplan-Meier survival methodology. To assess the potential influence of co-factors, the Cox proportional hazards model will be used. Continuous variables (e.g., percent reduction in wound area at 12 weeks post-treatment) will be compared between treatment groups using the Student's t-test. If the assumptions of the t-test are severely violated, a non-parametric alternative will be employed. Categorical variables (e.g., patient compliance at 3-month follow-up) will be compared between treatment groups using a chi-square test for contingency tables or a non-parametric alternative such as Mann-Whitney U test, as applicable.

The overall incidence of adverse events will be compared between treatment groups by the chi-square test for contingency tables.

Statistical significance is defined as $p < 0.05$. All analyses will be performed using the SAS software system.

A qualified statistician provided to the investigator(s) by the University of Pittsburgh Diabetes Institute Coordinating Center will perform all statistical analysis.

3. Population Definitions for Statistical Analysis

- a. **Evaluation for Efficacy Population:** The evaluation for efficacy population is defined as all randomized subjects who satisfy the study inclusion and exclusion criteria, does not become infected, receive a complete course of study medication as prescribed, complete all treatment visits according to schedule, and does not experience an adverse event that would lead to a withdraw from the study. This population will be used in the analysis of the protocol's primary endpoint, and will be included in the analysis of other efficacy and safety endpoints
- b. **Intent to Treat Population:** Efficacy analyses will be performed on this population in the same manner as for the Evaluation for Efficacy Population. Any subject, who is enrolled and randomized, whether or not he/she ultimately receives any study treatment, will be included in the intent to treat population. The following patient characteristics will qualify for the Intent to treat population:
 - Time to wound closure > 12 weeks
 - Patient no longer wish to participate in the study
 - Failed phlebotomy or failure to apply PRPG to the study wound for 2 consecutive weeks
 - Adverse Event leading to withdraw from the study
 - Treatment with immunosuppressive
 - Anticoagulant agents such as Heparin, Plavix or Coumadin
 - Needing radiation or chemotherapy
 - Those who develop infection, Osteomyelitis, or dermatitis
 - At the discretion of the physician for health reasons associated or not associated with the study
 - Wound recurrence at any time between end of treatment and the 3-month follow-up visit.
 - Wound increase in size $\geq 30\%$.
 - Wound enlarges on two consecutive visits
 - Co-morbidities
 - Develops an occurrence of an additional wound within 3 cm of the study wound
 - Study extremity requires revascularization or amputation
- c. **Evaluation for Safety Population:** All subjects who receive at least one study treatment, partial or complete, (including subjects who experience an adverse event) will be evaluated for safety.

VII Risks and Benefit

In 2003, the Center for Medicare and Medicaid Services (CMS) conducted an extensive literature review seeking evidence for determining coverage for autologous PRP therapy. CMS concluded that, in the absence of reliable data, the evidence is not sufficient to approve coverage for the use of PRP in patients with chronic, non-healing wounds. The safety, efficacy, and effectiveness of platelet gel therapy in the diabetic patient population

warrant further investigation in controlled clinical trials. This study will seek to build upon previous work in platelet derived growth factor therapy providing evidence sufficient to determine if technique modifications will measurably improve wound-healing outcomes in patients with chronic diabetic neurotrophic lower extremity wounds. There may be no direct benefit from participation in this study. The major risk is that the wound may not heal either with standard therapy or with PRP gel.

Autologous Platelet Gel (APG) involves steps that introduce risk to the patient; an approximate 40 ml. whole blood draw, combining the Platelet Rich Plasma (PRP) portion of the draw with autologous thrombin and calcium chloride in a 10:1 ratio, and topical application. When a phlebotomy is performed there is a risk of bruising, soreness, or rarely, infection. Infection occurs in 5-7% of patients with diabetic wounds present for more than one month. After the blood is separated the PRP is combined with calcified autologous thrombin and topically applied to the wound. During this process there is a 1-10% incidence of itching, hives, nausea, and vomiting. Rare occurrence of allergic reaction to the ethanol contained in the activAT processing syringe has been reported.

The potential benefit is improved wound healing.

VIII Administrative Requirements

A. Study Monitor

While the Investigator will have the overall study responsibility for the management and monitoring of this investigation, a Contract Research Organization (CRO) or other qualified individuals may be utilized to assist with some aspects of conducting and monitoring the study.

C. Investigator and Staff Responsibilities

All investigators and researchers will be required to complete the governing IRB(s) research certification(s). These certifications will be attached to the study protocol and placed on file with the University of Pittsburgh Diabetes Center and the IDSMB.

1. Principal Investigator

The Principal Investigator is the person responsible for the conduct of the clinical pilot study at a study center. The responsibilities of the Principal Investigator include but are not limited to: obtaining patient informed consent, complying with the Investigational Plan and applicable FDA and other regulatory regulations, overseeing the administrative activities, study data collection, and the activities of the sub-investigators and other staff involved in conducting the study.

2. Sub-Investigator

A sub-investigator participates in the study (e.g., obtains patient informed consent, conducts patient examinations) under the direction of the Principal Investigator.

3. Research Coordinator

The research coordinator assists with clinical study activities as assigned under the direct supervision of the Principal Investigator. The duties of the research coordinator may include ensuring that the required tests and evaluations are done for each patient at the required intervals, completing the case report forms based on the medical records, assisting with administrative activities, and scheduling patient follow-up appointments.

D. Investigator Agreements

The **Investigator Agreements** (Appendix F) are written agreements to be signed by the Investigators that define their responsibilities.

D. Monitoring Procedures

Study Initiation: All personnel expected to be involved in the conduct of the study will undergo an orientation to include review of study protocol, instruction for record completion, and overall responsibilities.

E. Investigational Device Charge

The devices to be used in this clinical study will be loaned to the investigational sites by BioTronics, Inc. at no charge.

F. Laboratory Accreditation

Any laboratory facility to be used for analysis of routine clinical laboratory samples required by this protocol must provide evidence of adequate licensure or accreditation. Reference values and/or normal ranges for the test results used in conducting this protocol must be provided

G. Institutional Review Boards

This protocol, the proposed informed consent form, and any method used for patient recruitment must be reviewed and approved by the appropriate Institutional Review Board(s) (IRB(s)) prior to the start of the study. During the course of the study, the Principal Investigator will make timely and accurate reports to the IRB(s) on the progress of the trial at intervals not exceeding one year, as well as satisfying any other local IRB(s) regulations regarding reporting. Furthermore, at the completion or early termination of the study, the Principal Investigator must make final report to the IRB(s) within the applicable IRB(s) time frames.

Any significant changes or revisions in the study protocol or any changes that may alter patient risk must be approved in writing by all appropriate IRB(s) prior to implementation. A protocol change intended to eliminate an apparent immediate hazard may be implemented immediately prior to and approval by the IRB(s).

Institutional Review Boards/Authorization Agencies

- University of Pittsburgh Medical Center
- Wilford Hall Medical Center

- Surgeon General of the United States Air Force (2nd level approval)

H. Informed Consent

The proposed informed Consent form, which must be in compliance with regulatory regulations, must contain all of these items:

- A complete explanation of the purpose and nature of the study.
- A description of the procedures.
- Possible advantages and risks.
- Alternate treatment options.
- A statement of confidentiality concerning patient study records.
- A statement regarding voluntary compensation and availability of treatment in the case of injury.
- An explanation of whom to contact about the research.
- The patient's rights.
- Notification that participation is voluntary and refusal will involve no penalty or loss of medical benefits.

These requirements are in accordance with the Federal Regulations as detailed in the 21 CFR 50.25 and the Declaration of Helsinki. The informed consent form should also indicate by signature that the patient, or where appropriate, legal guardian/representative, permits access to relevant medical records by representatives of the U.S. Food and Drug Administration (FDA) or other applicable regulatory agency and the Investigator and /or the Investigator's duly appointed agent, included the University of Pittsburgh Diabetes Institute Coordinating Center. The informed consent must be in the patient's primary language.

The investigator will be responsible for obtaining written informed consent from potential patients prior to any study specific screening and entry into the study. The investigator will retain the original. A copy of the signed document will be provided to the patient and a copy will be maintained with the patient's study documentation.

I. Records and Reports

1. Record Retention

The Investigator must maintain records of source documentation and all documents related to this investigation for at least 7 years after completion of the study. Additional information concerning record retention will be defined within the Data and Safety Monitoring Plan

2. Documentation

A log of all patients evaluated for this protocol must be maintained at each site. An explanation for any patients excluded from enrollment will be provided. Patients who sign an informed consent form and are enrolled under this protocol will be assigned a study subject identification number. This study subject identification

number will be used to identify the subject on all case report forms, study photographs, and other study-related documentation.

For each individual treated under this protocol, the site Project Manager is required to prepare and maintain case histories in the patient chart that include all source documents needed to verify the accuracy of all observations and other data pertinent to the investigation. This will include all source documents needed to verify the accuracy of all observations and other data contained in the CRFs on each study patient.

The treating physician or his or her designee is required to retain the records related to the trial for at least 7 years after completion of the study. If no application is to be filed or if the application is not approved for such indication, the records must be retained until 2 years after the investigation is discontinued and the regulatory agencies are notified.

3. Principal Investigator's Final Report

Within 3 months following completion of the study, the Principal Investigator will be responsible for completing a final report containing a description of the outcomes of the study at his/her institution with respect to number of patients evaluated for the study, patient enrollment, serious adverse events, number of patients withdrawn, and reasons for withdrawal. This report will be made available to the Investigator, IRB'S, Surgeon General's Office of the United States Air Force, and the University of Pittsburgh Diabetes Institute Coordinating Center.

4. Disclosure of Data

All information obtained as a result of this study or during the conduct of this study will be regarded as confidential. Disclosures (i.e., any release of information to any third party not noted herein) of any information not previously known to be public and/or results of the investigation for publication or by oral or poster presentation shall not be made earlier than thirty days after submission of the proposed material to the Investigator for inspection, unless the Investigator consents to earlier disclosure. The Investigator will take appropriate notice suggestions before disclosure for publication or presentation consistent with protection of the Patient's right to its confidential data.

J. Patient Confidentiality

The Investigator will keep all data related to patient identification in strict confidence. Patient identity will not be revealed in any of the reports or publications resulting from this study.

L. Investigational Plan Modifications

Any changes to this protocol, that affect study objectives, study design, study procedures, patient population, or significant administrative procedures, will require a formal amendment to the protocol. Applicable regulatory agencies and the IRB must approve certain changes before implementation. Prior to implementation, an amendment must be agreed upon by the Principal Investigator, and approved by the

applicable regulatory agencies and IRB. If the informed consent is affected by the changes, the investigator will be responsible for ensuring that all enrolled patients are notified and given the opportunity to sign a revised form

General administrative changes to the protocol are minor corrections and/or clarifications that do not affect the manner in which the study is to be conducted. Such administrative changes will be agreed upon by the Principal Investigator and will be documented in a memorandum. At the discretion of the Principal Investigator or his designee, the applicable IRB may be notified of administrative changes according to applicable IRB guidelines.

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X Appendices

Appendix F
Teleophthalmology &
Evaluation Documents 2006

**Teleophthalmology
Evaluation Team
TopCon Camera and LAN
Assembly Manual 2006**

TopCon Camera and LAN Assembly Manual



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- **TopCon Camera Set-up.....4**
- **Computer Set-up.....10**
- **Power On Steps.....16**
- **Important Notes.....16**
- **Network and Sign On Information.....16**

Teleophthalmology Equipment

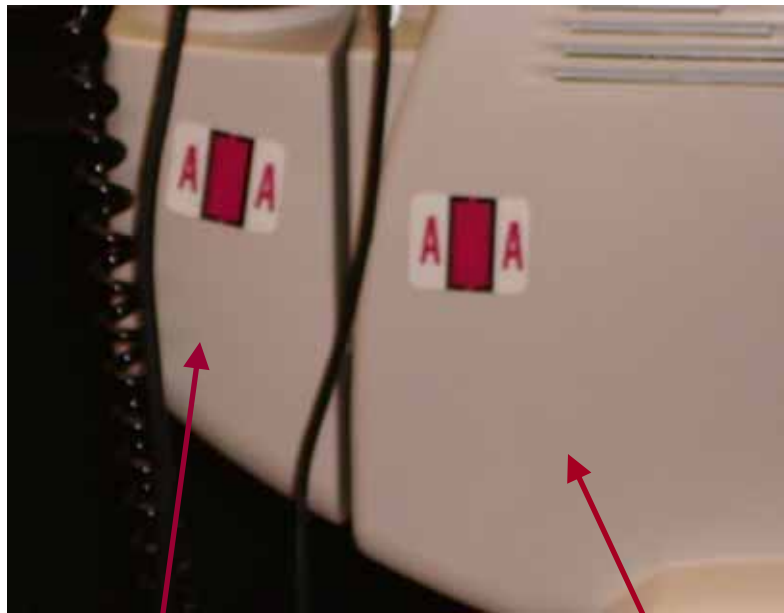
- 1 router with power supply
- 1 TopCon camera table
- 1 TopCon camera
- 1 Nikon camera and interface assembly
- 1 keyboard
- 2 mouse (1 for TopCon computer, 1 for tablet PC)
- 1 IBM T-43 Thinkpad laptop (server) with power cord
- 1 IBM X-41 ThinkPad tablet (registration) with power cord
- UPS device – white power box
- 25' Cat-5e or Cat 6 Ethernet cables
- 1 roll of duct tape
- 2 stools (1 for photographer, 1 for participant)
- cart for moving TopCon camera in case

Important Contact Information

- Steve's Cell: 412-779-9106 (weak signal while in office)
- Work: 412-692-4130
- Pager: 412-958-6501

TopCon Camera Assembly

- Select a good location for the camera. Remember to keep in mind the length of cord and the light requirements (dark) for the camera.
- Place the TopCon camera base onto the Topcon camera's table so that the imager's side of the camera is facing the hole in the table.
- **A: Attach the Nikon camera housing to the TopCon camera base. Once camera housing is correctly attached, LOCK the camera into position using the locking mechanism located at the top of the housing.**



**Nikon Camera
Housing**

**TopCon
Camera Base**

TopCon Camera Assembly (cont'd)

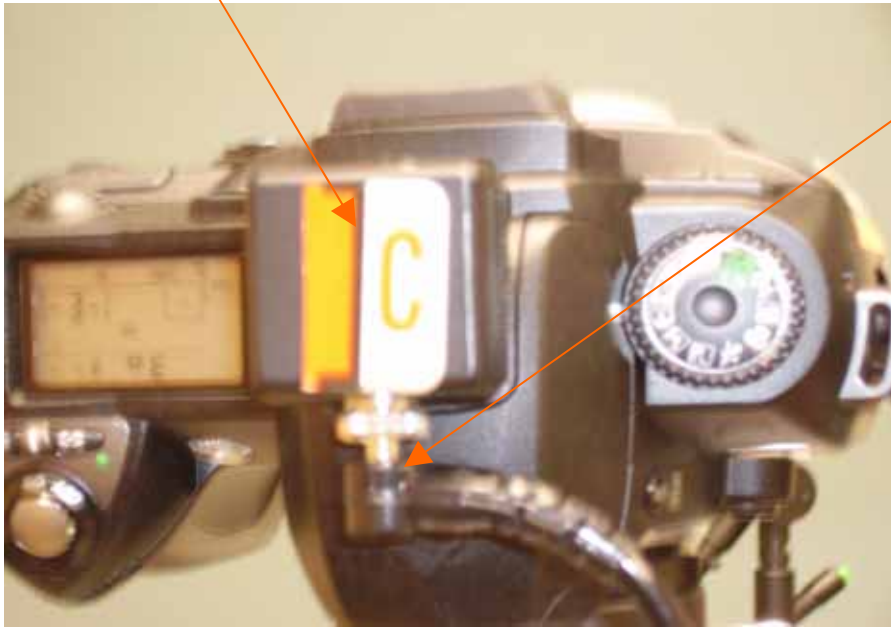
- **B: On the Nikon camera, place Nikon power cord (cord B) into the DC in hole of the camera.**
 - Run the cord through the hole on the table and connect to the EH-5 power supply
 - Run the AC cord from the power supply to the gray chloride power protector (white power box)
 - Place plug into orange labeled socket.



TopCon Camera Assembly (cont'd)

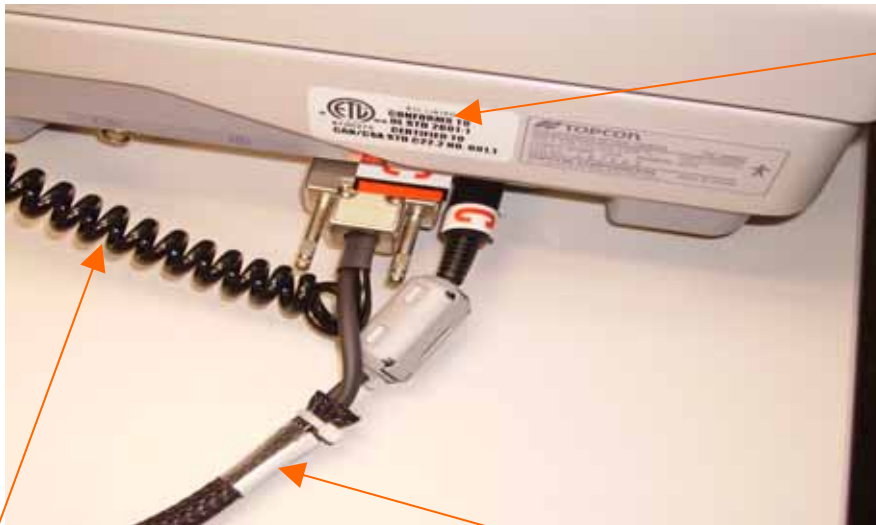
- C: 1. Attach the Nikon flash cord to the Nikon camera.

Side of Camera Facing Imager



Nikon Flash Cord

- C: 2. Attach the other end of the Nikon flash cord to TopCon camera base.



TopCon Base

Flash Cord from Camera

TopCon Nylon Cord to Computer

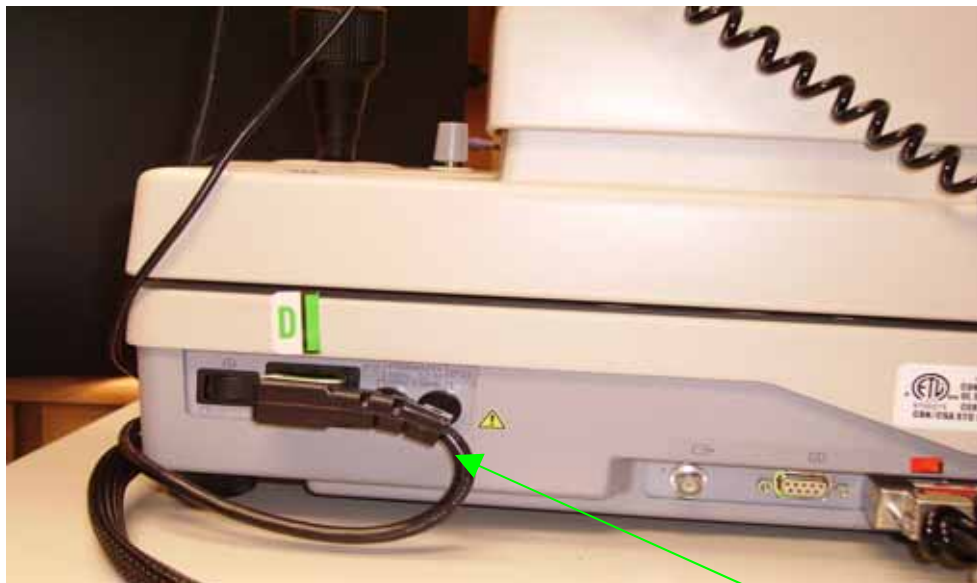
TopCon Camera Assembly (cont'd)

- C: 3. Run the TopCon nylon cord to back of TopCon computer.



TopCon
Nylon
Cord from
TopCon
Camera

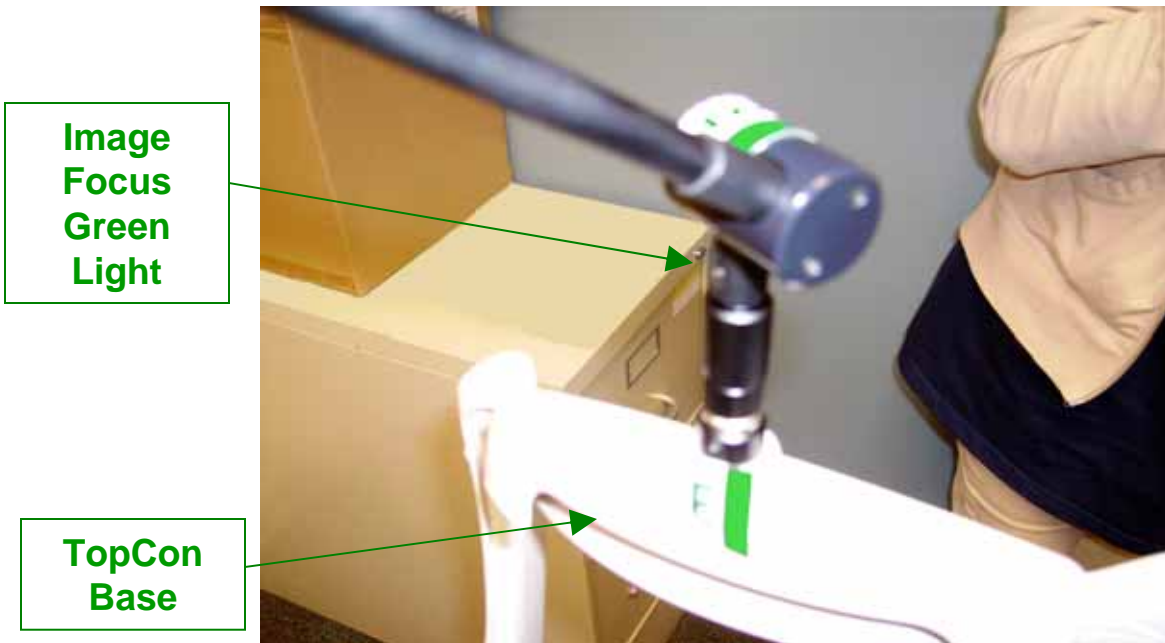
- D: Run the power cord from the TopCon base to the chloride power pack and insert the plug into the green labeled socket.



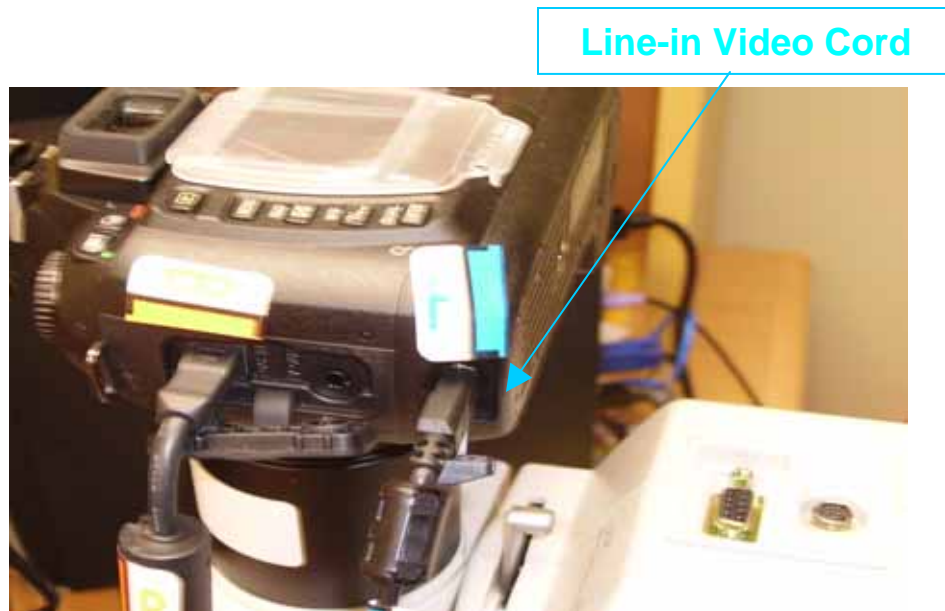
Power Cord

TopCon Camera Assembly (cont'd)

- **E: Attach the image focus green light to the TopCon base.**
 - Be sure to line up the A, B, C holes as well as the notch correctly before screwing the green light onto the base.

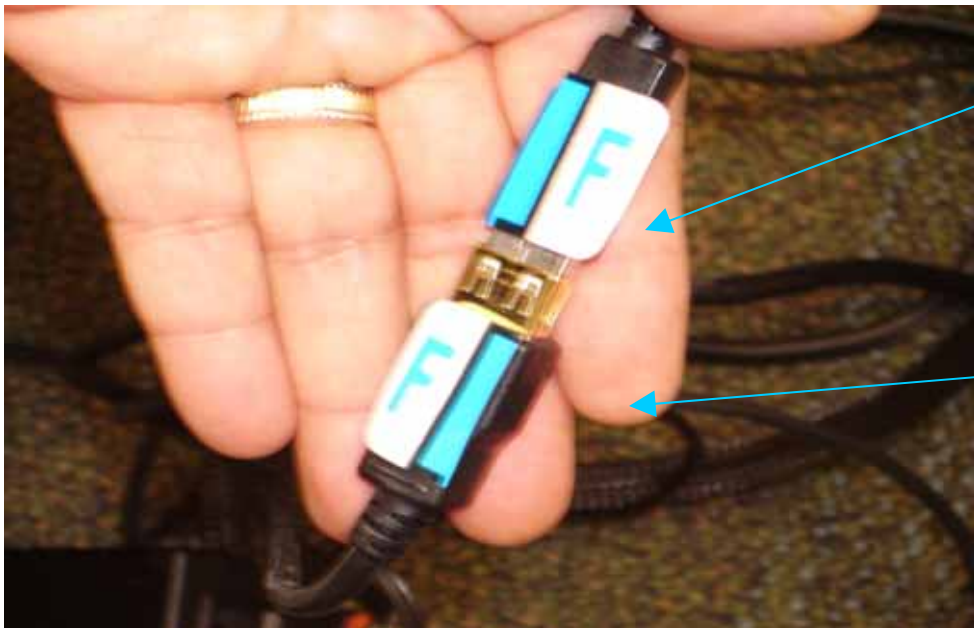


- **F: 1. Attach the line-in video cord to the camera.**



TopCon Camera Assembly (cont'd)

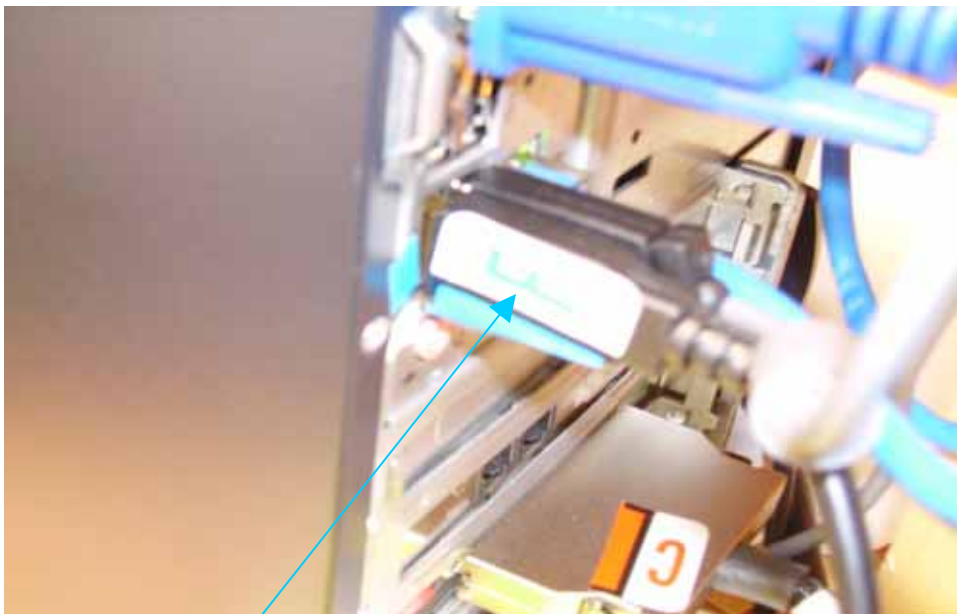
- **F: 2. Attach the line-in cord from the camera to the adapter.**



Adapter
to Free
USB Port

Line-in
Video Cord
from
Camera

- **Run the adapter cord to a free USB port on the back of the computer.**



Cord from
Adapter

Computer Set-up

- **G: 1. Attach the computer power cord to the back of the computer.**



Computer
Power
Cord

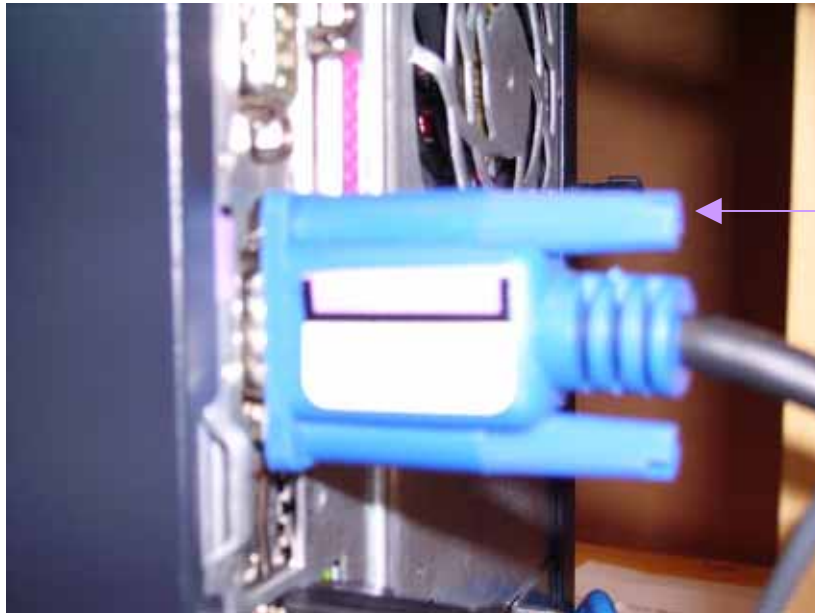
- **G: 2. Connect the power cord from the computer to the gray chloride power box.**



Power Cord
from Computer

Computer Set-up (cont'd)

- **H:** Attach the Monitor line from the back of the computer to the back of the monitor.



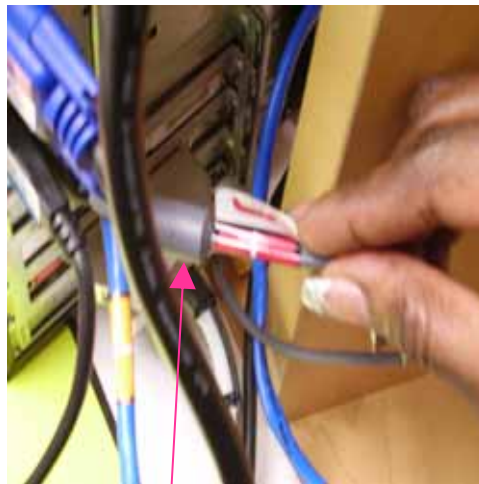
Monitor
Line



Monitor Line
in Back of
Monitor

Computer Set-up (cont'd)

- **I:** The keyboard cord (I) connects to the back of the computer and is purple.

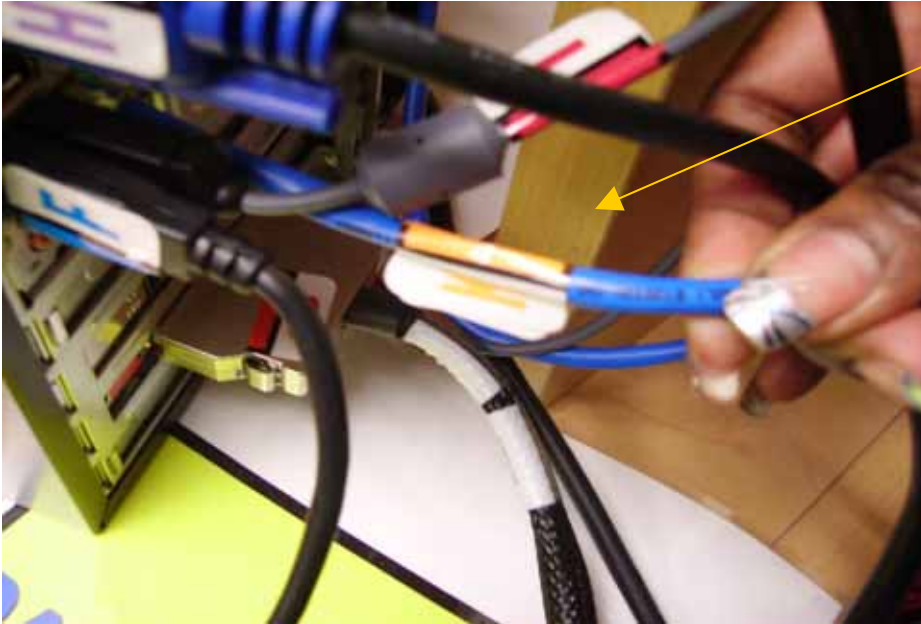


Mouse Prong

- **J:** The mouse has a gray prong and plugs into the back of the computer.

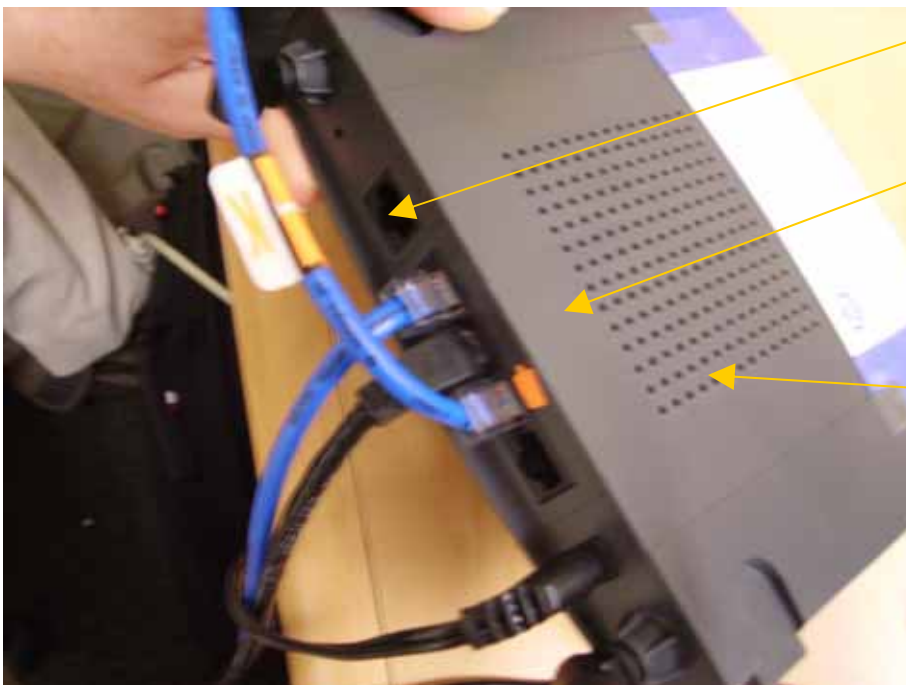
Computer Set-up (cont'd)

- **K: 1. Connect a blue Ethernet cable to an Ethernet port in the back of the computer.**



Ethernet Cable

- **K:2. Run the Ethernet cord from the computer to the router, which should be located in a central position.**



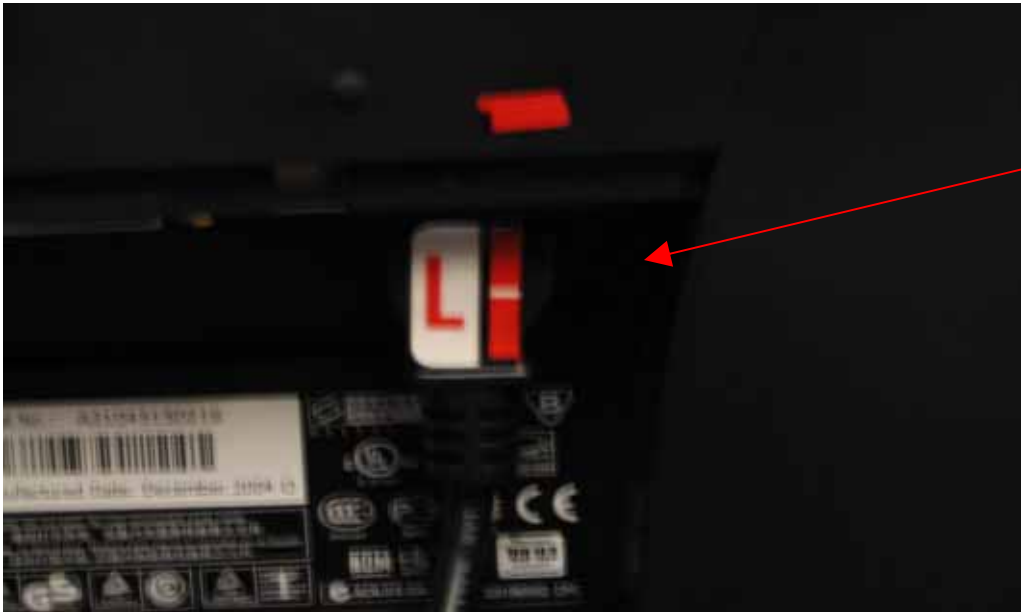
Ethernet Cable

Ethernet Cable Port

Router

Computer Set-up (cont'd)

- **L:** The computer monitor also has a power cord. This power cord connects next to the monitor line (blue prong). Once this cord is plugged into the monitor, plug the opposite end into a chloride power pack.



**Monitor
Power
Cord to
Power
Source**

- **M:** Attach a long Ethernet cable to the Ethernet port of the registration tablet (small laptop).

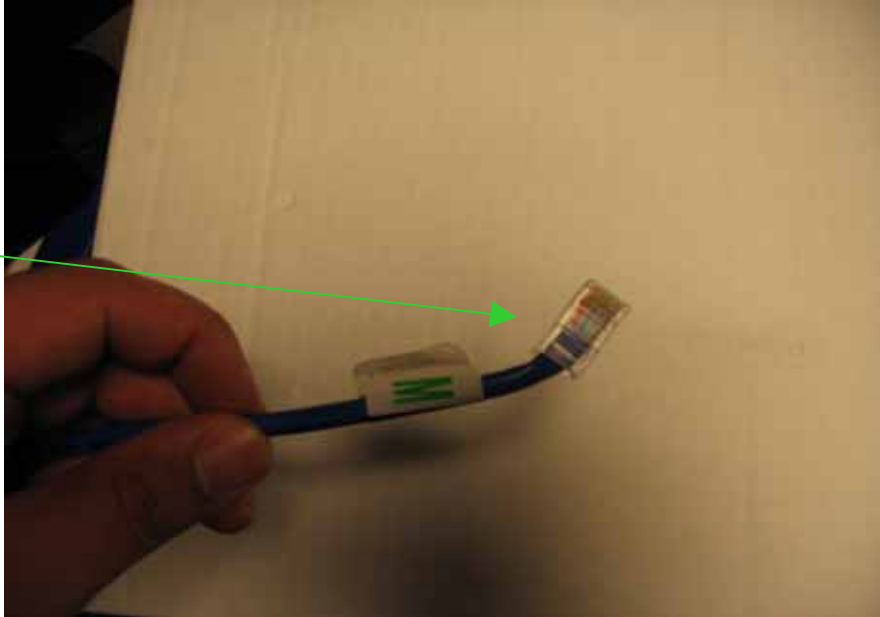


**Ethernet
Cable Port on
Registration
Laptop**

Computer Set-up (cont'd)

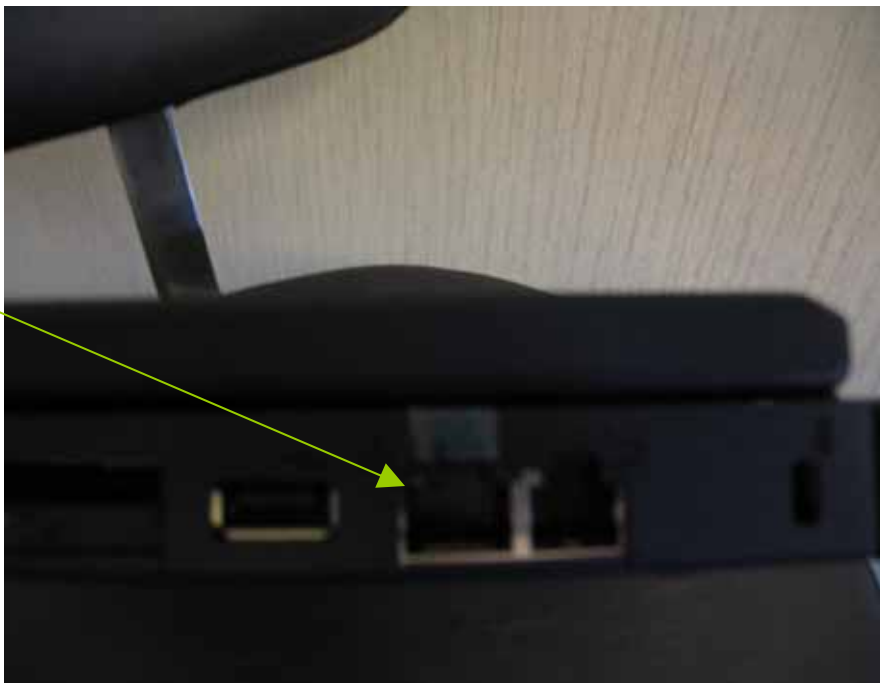
- **M: Run the Ethernet cable from the registration laptop to the back of the router.**

Ethernet
Cable from
Tablet to
Router



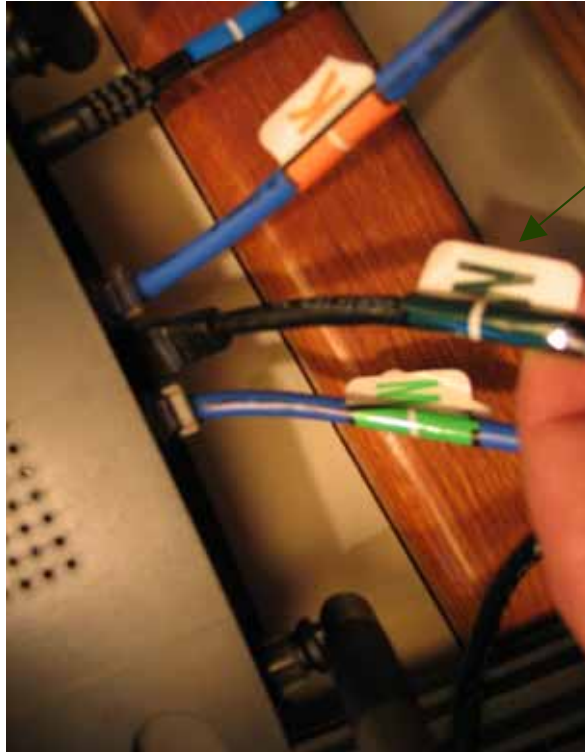
- **N: Connect an Ethernet cable to the back of the server (large laptop).**

Server
Ethernet
Port



Computer Set-up (cont'd)

- **N:** Run the Ethernet cable from the server to the router.



**Ethernet Cable
from Server to
Router**

- **O:** Connect the router power cord to the back of the router.



**Router
Power Cord**

Computer Set-up (cont'd)

- **O:** Run the power cord from the router to an outlet.



Router
Power Cord

- **P:** Connect the server power cable to the server (large laptop) and then to the corresponding AC adaptor. Once this is done, plug the AC adaptor power cord into a power source.



Server
Power
Cable from
Server to
Outlet

Computer Set-up (cont'd)

- **Q: Connect the mouse to the registration tablet (small laptop)**



Mouse
Connects
to Small
Laptop
USB Port

- **R: Connect the registration tablet's power cord to registration tablet and then to a power source.**



Registration
Tablet
(Small
Laptop)

Power On Steps

1. Turn on Digital (Nikon) Camera
2. Turn on TopCon Camera
3. Turn on Server (Large Laptop)
4. Turn on TopCon Computer
5. Turn on Tablet PC (Small Laptop)

Important Notes

- The server (large laptop) should NOT be used for registration. Registration using the server could result in the server freezing and the loss of images/data.
- Do a dry run to make sure everything works as expected

Network & Sign On Information

- Servers IP Address: 192.168.1.2
- Domain: IMITS-T43-A
- Username: Administrator
- Password: remoteis

Teleophthalmology Evaluation Team Site Visits 2006

**Temple Emanuel
Diabetes Symposium
McKeesport Palisades
Fairchance Site
Yablonski Site
Uniontown Hospital
Carmichaels Site
Indiana Regional Medical Center
Lincoln-Lemington Family Health Care Center**

Evaluation Report

Temple Emanuel

March 5, 2006

Site Description:

This diabetic retinopathy screening took place at the Temple Emanuel. It was located in an affluent section south of Pittsburgh. In an attempt to give back to their community the temple held their first health fair. This was also the first health fair which included the retinal screening van. Schedule for the health fair was 9:00-12:30.

Attending Personnel:

Steve Uttecht
Barb Mack
Monica Cassimir
Larry Jefferson
Robb Wilson

Summary

Set-up took from 8:00-9:30 and the location was a coatroom. It was the darkest place to image and still remain relatively close to traffic coming and going through exhibitors. This was their first attempt at a health fair. Large open area was fairly populated with exhibitors but attendance was poor. Many adults that came through were there to pick up children from Sunday School.

Retinal screening was not mentioned on temple flyers but did appear on posters and on their website. Temple posters stated free vision tests for children and adults. Sign(s) were needed to identify retinal screening registration area. The signage used at the Healthy-4-Life Expo would work. Wilson will contact Gerri Weiss UPMC PR) to find out how to obtain.

Need cart to move camera equipment. Mack will check on order. A borrowed dolly worked well for tear down. Thirty minutes for tear down. Because of location the wires were just long enough. Uttecht will determine what extension cords are needed. Coatroom was not dark enough. A tablecloth was taped to entry way to prevent light entering. The positioning of the camera, facing out of the room added to the light problem but because of the coatroom setup could not be better positioned.

Three participants were imaged. The first participant's images were poor due to inefficient dilation and/or cataract problem. Participant will return in April to one of the clinics to try again. The other two participant images were fine.

Needs

1. Cart or dolly to help move equipment safely and quickly.
2. Extension codes both electrical and for the computer.
3. Flexible plastic/nylon tarp to remove light from entering area.
4. Signage to identify area or table e.g. Eye Screening For Diabetic Retinopathy.
5. Uniform shirts for staff to identify them as part of the study.
6. Duct and masking tape.
7. Small portable table(s) or stand(s) for other equipment e.g. camera monitor.

Evaluation Report

Diabetes Symposium – Quality Inn, Bedford PA

March 16, 2006

Site Description:

The event was a diabetes symposium sponsored by UPMC and located at the Quality Inn in Bedford, Pennsylvania. Participants were pre-registered for this event. There were approximately 200 people present at this event, most of which had diabetes or were “borderline” diabetic. The event started around 9:30am, and the retinal screening equipment van arrived at the same time. Symposium was scheduled from 9:30 to 3:30.

Personnel Attending:

Larry Jefferson
Barb Mack
Russ Silowash
Robb Wilson

Summary:

At the beginning of the symposium, Mack made an announcement about the diabetic retinopathy screening, and that brought a rather positive response from the crowd. Mack was able to hand out consent forms to approximately 30 individuals. .

The retinal screening team was also outfitted with uniformed t-shirts in order to look more professional.

The retinal screening was set up in the “Library Room” of the Quality Inn. This room was rather large, and it had adjustable lighting. Having a large dark space for the imaging to occur was not a problem at this location.

The physical set up of the equipment took approximately one hour to complete. The staff was able to conceal most exposed wires with duct tape. Extension power cords were also implemented to get maximum reach of the equipment. The camera came on a cart with wheels, however, the cart seemed too small for the box, and was still rather clumsy. There were some set-up difficulties concerning the camera, and router. The retinal screening team also experienced server problems that initially inhibited them from properly registering participants. This problem took approximately one hour to fix. The team had to call Steve Uttecht at his office in order to fix these problems. Screening began at 11:45am.

The imaging room was set up for one person to enter the room. The person would then be registered. Once the person was registered, a series of images were taken of the participant’s eyes. Upon finishing the images, the participant was given the option to

view their eye images. The participant was then escorted out of the room, and the next participant was brought in. One person entered the room at a time in order to insure patient privacy and HIPAA compliance. Once this process was planned out, the imaging process became more efficient. As participants were waiting to register, Wilson had the participant sit outside of the “Library Room” to read over/initial the consent form. This made the consent process more time efficient, because the participant had already read over the consent form prior to registration. If the participants had any questions concerning the study, they could ask the staff during the registration process.

The retinal screening team was able to image 27 people from the times of 11:30 to approximately 4:00pm. Seven people who originally consented did not show for their imaging. Tear down took approximately 30 minutes.

Needs:

1. **Equipment arrival should be earlier** – In order to help eliminate technical problems the equipment should arrive earlier than the beginning of the individual program. By doing this, setup and technical difficulties can be completed before the start of the individual program. The symposium finished at 3:30pm; however, the imaging team did not get done imaging the participants until around 4:00pm. This could have been avoided if the equipment was set up earlier. Also, 7 participants were not imaged, because they did not show up for imaging. This too may have been avoided by early set-up.
2. **Physical Set-up Descriptions** – The directions for setup should be more precise and detailed. Jefferson came up with a labeling system that would be beneficial to the physical setup. By putting lettered labels on all the equipment and their proper hookups, set-up time could be reduced and problems could be avoided.
3. **Technical difficulties** – Server problems were not easily fixed. A computer specialist could be assigned to the team for such problems. Also, a mach set-up could be performed prior to the event to insure that the equipment and programs will work properly.
4. **Registration** - Registration could have been separate from imaging in order to speed up the entire process. Longer CAT-5 Ethernet cables or barrel connectors could be obtained to enable a longer range of equipment. Another option is having the wireless tablets for registration. This would enable the separation of the registering process from the imaging process. It must be kept in mind that a separate, but private section needs designated for registration in order to insure participant privacy.
5. **Staff Roles** - During a large imaging session such as this one, staff could switch roles or take breaks. When a person does one task for long periods of time, he/she could become tired, stressed, and less efficient. If people switched roles every so often, efficiency could be kept at a high, constant level.

Blank Page

Evaluation Report

McKeesport Palisades

July 18, 2006 and July 19, 2006

Site Description:

This particular health fair was located on the second floor of the Palisades Building in McKeesport, Pennsylvania at 501 South Water Street. The second floor of the building was approximately sixty feet by one hundred feet in size, resulting in a rather large area that could host a significant amount of people. The retinal screening area was located at the far left corner of the complex. The health fair was scheduled from 9:00 to 7:00 on July 18th and from 9:00 to 2:00 on July 19th.

Attending Personnel:

Barb Mack (both days)
Russell Silowash (both days)
Robb Wilson (1/2 day on July 18th)

Summary:

July 18th: Silowash arrived at the Palisades building at approximately 7:45 am. The retinal screening van was already there at the time of arrival. The van was unloaded at 8:00 am due to parking problems at the facility; the van had to be on a level surface before unloading, and one was not available until the reported unloading time. The van had become easier to unload at this health fair compared to previous health fairs due to the implementation of a storage cart that housed all of the computer equipment needed for the camera apparatus. Once all of the equipment was moved to the second floor of the facility, set-up began. The camera system was set-up in a relatively dark area directly behind the registration table. The camera and the registration table were separated by a dark blue curtain. Opaque screens were borrowed from the facility to surround the camera system in order to block any light from entering the area. The TopCon Camera and LAN Assembly Manual was used when needed. Once the camera and computer systems were set-up properly, the system was powered on in the order provided by the manual. By doing this, there were no problems with the LAN, computer, or camera. Test photos were taken, and registration started promptly at 9:00a.m. Due to the lack of personnel, both Mack and Silowash registered participants. The event was well received by the general population, and the screening area became rather busy. Most of the participants that completed imaging were asked to complete the Diabetic Retinopathy Screening Survey. The survey was well received, and everyone that was asked to complete the survey did so very willingly. Due to the system working properly, there was no long waiting periods for the participants. Once the entire participant's information was entered into the notebook, they could be imaged right away. The only time a participant had to wait was when someone ahead of them was getting their images done. The waiting did not last more than a few minutes. Twenty-eight people completed screening on this day. Once 7:00 pm arrived, the system was shut down, but only the registration equipment and server were disconnected. These items were locked in the storage cart.

July 19th: Silowash arrived promptly at 8:30 am. The retinal screening van arrived shortly after. Only the registration notebook and server had to be set-up on this morning. Once again, the system was powered on in the order according to the assembly manual, and the system worked on the first time again. This day went very similarly to the day before with Mack and Silowash both registering participants. The day started out busy, but there were no problems encountered during the entire health fair. Once again the surveys were completed by most of the people completing the screening process. If the retinal screening table became busy, people were

sometimes missed for the survey. Nineteen people completed screening on this day. The health fair ended at 2:00 pm, and breakdown and loading of the TopCon camera and computer system took about an hour.

Needs:

1. **Black Cart** – The black cart purchased for this program was supposed to be used as a storage center for a working hub; the person in charge of set-up would only have to plug the cart in, and the system would work properly. This was not the case for this health fair. The cart was only used as a storage space for all of the computer equipment. Even though this made unloading and loading the van much easier and efficient, the cart would really be beneficial and more efficient if it was used as it should be.

Solution: Steve Uttecht was appointed in charge of this project. Both carts purchased (one clinic and one for community activities) will be assembled for its proper purpose. Silowash volunteered to help.

2. **Protocol Violation** – It was found that some people completing screenings were not Type 1 or Type 2 diabetic. Some people had family histories of diabetes or were “borderline” diabetic. Registering these people into the study went against IRB protocol.

Solution: Dr. Janice Zgibor was notified of this protocol violation, and the Unintentional Event Form to the IRB will be completed immediately. Dr Zgibor will send an employee to each of the remaining health fairs in order to monitor IRB compliance. Registration participants will each go over the protocol to refresh themselves with the protocol.

3. **Rewards** – As part of the program, eyeball key chains were given to people who completed the screening process. However, during this health fair, the eyeballs were within general public reach; anybody walking past the table would grab a key chain and/or magnifying glass.

Solution: More eyeball key chains may have to be purchased. However, we will only give these rewards to people who have completed the retinal screening. This will be accomplished by having the key chains in a more private location, such as near the camera apparatus

4. **Office Supplies** - Multiple office supplies need to be purchased for this project in order to maximize efficiency and small work environments. Below is a list of items that should be considered.

1. Duct tape – could be used to tape down any wires that may trip participants and staff.
2. Plastic Mail Bins – could be used to separate completed and uncompleted consent forms. The work area often became cluttered with consent forms.
3. Extra Pens
4. Push Pins – could be used to hang additional posters if sites warrant such.

5. **Poster Problems** – The poster designed for the health fairs could not stand up on its own, and had to be propped up against a more permanent fixture i.e. a table. This may have resulted in less publicity for our project because only people approaching our table from one angle could see the poster.

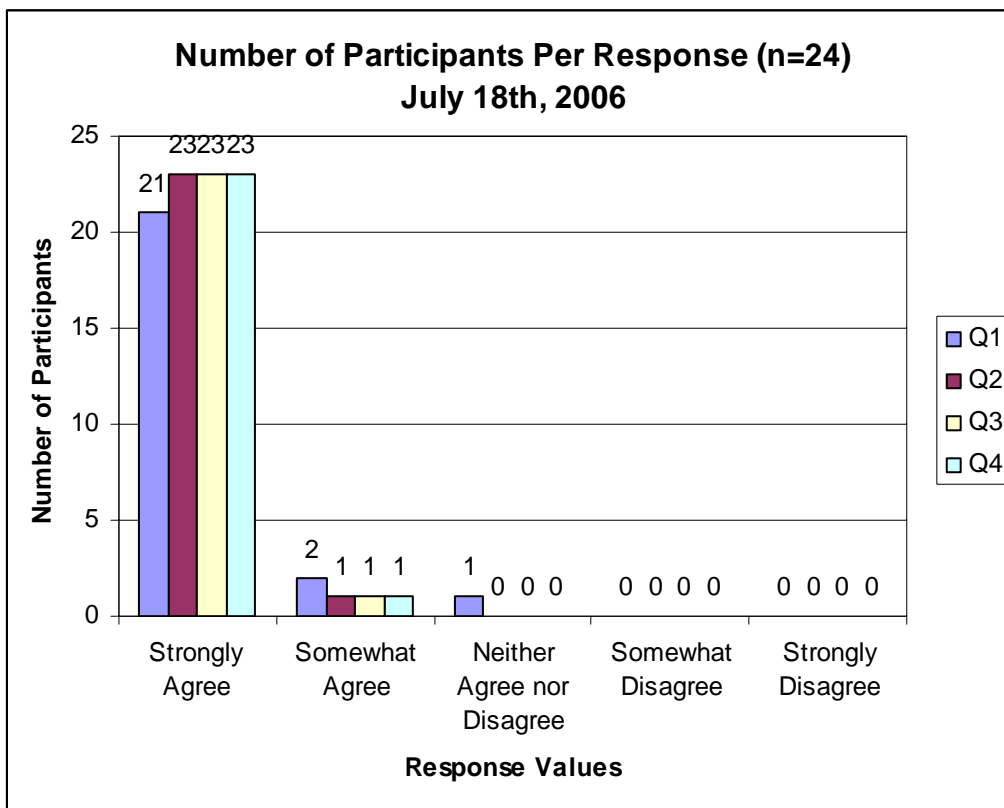
Solution: The poster’s backing could be permanently fixed to the poster (with glue or some other adhesive). Also, we could have multiple posters to cover many viewing angles.

Survey Results:

July 18th: 24 people completed the survey out of 28 screening completers (85.7%). Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on each of the graphs.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concerned for me.
3. I was comfortable with the way the equipment and camera were used.

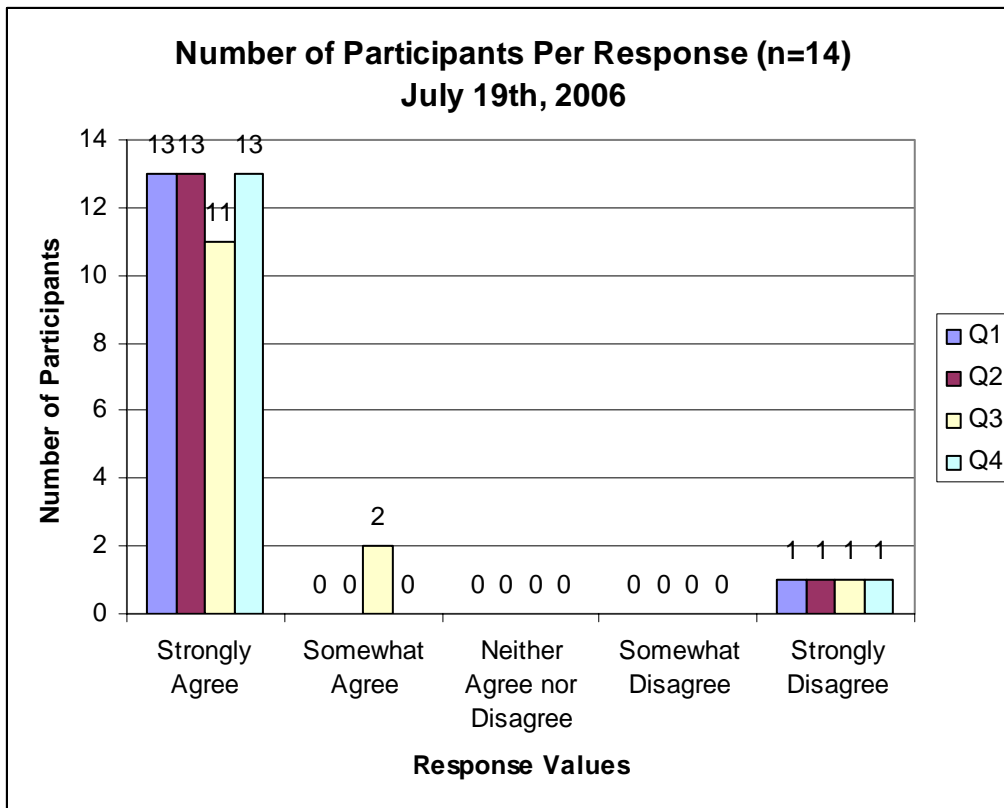
4. The wait time for my retinal photographs was acceptable.



Key Quotes/Comments:

- “Everyone was professional and friendly.”
- “It was wonderful; it gave me a sense of wellbeing concerning my vision.”
- “I have limited insurance coverage – thank you!”

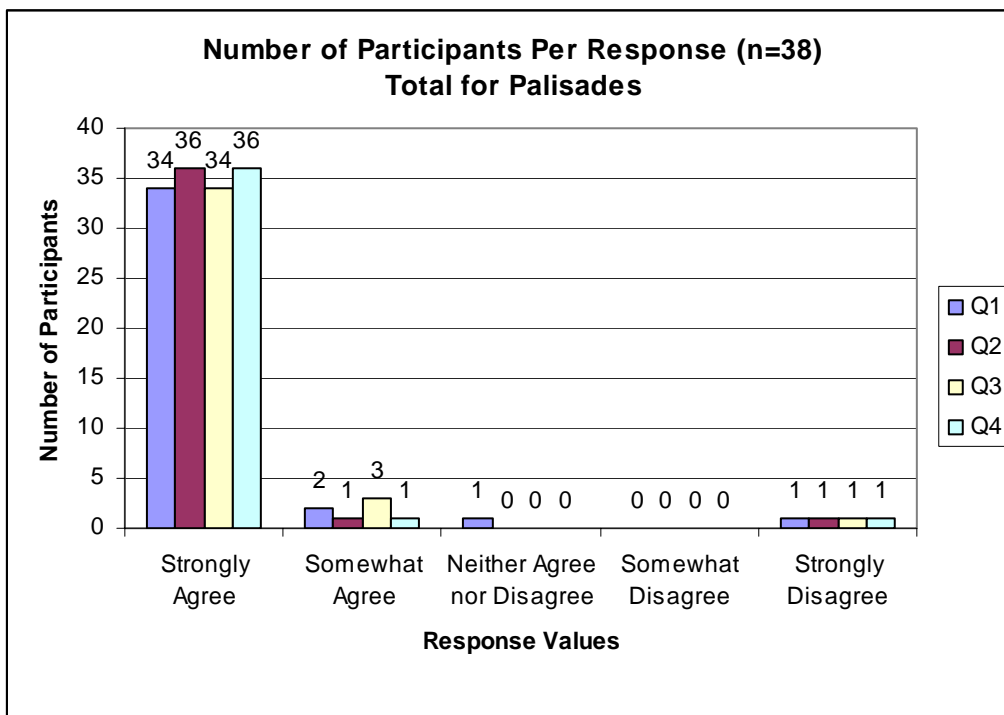
July 19th: 14 people completed the survey out 19 people that completed screening (73.7%)



Key Quotes/Comments:

- “Thank you for bringing this to the UPMC fair.”

Totals: 38 out of 47 total participants completed the screening survey (80.9%)



Evaluation Report

Yablonski Health Clinic

August 9, 2006

Site Description:

The Yablonski site was a small, community clinic located in Frederick, Pennsylvania. The event took place from 10:00 am to 12:00 pm.

Attending Personnel:

Barb Mack
Leslie Anthony

Summary:

The location was somewhat difficult to find because of the unfamiliarity of the area and the size of the site. The retinal screening van arrived at about 9:20 am. Like the previous site, this was a small, community clinic. A diabetes educator and a foot specialist were also seeing people at this event. Most of the participants were contacted by clinic staff and encouraged to attend. Modifications made to make the equipment cart to make it more manageable; once it was moved from the van to the imaging room in the clinic, it was quickly assembled and ready for imaging. The camera and computer were set-up in one small exam room that was conducive for imaging; window blinds were drawn and darkened the room adequately. The room across the hall was set-up for participant registrations.

Retinal screenings were conducted from 10:15 am to 12:15 pm. Ten of eleven individuals were confirmed eligible for participation. One participant stated that he was a “borderline diabetic”, but when asked, reported a blood sugar level of 130. He was enrolled in the study. Another participant was clearly unable to comprehend the consent process but his mother, who was accompanying him, stated that she was his legal guardian. Upon further questioning, staff discovered that she was not a “legally” appointed guardian. This person was not enrolled in the study.

In general, Anthony reviewed the consent process and registered participants and Mack assessed pupil size and imaged participants. Both Anthony and Mack confirmed eligibility for all participants. Mack indicated that some duplicate registration records were appearing for people. This issue was likely related to the “learning curve” of the registrar. The equipment remained assembled and ready for screening to be conducted at the same clinic on the following day – no breakdown was required.

Needs:

1. **Camera case** - The camera equipment is heavy and difficult to manage. Currently it requires lifting the equipment (weighing approximately 75 – 100 pounds) from the carrying case to the table top. This could be considered a liability. We should explore alternative options, such as mounting the TopCon equipment on the table.
2. **Black Cart** – This was the first event to follow work that had been done to fully assembled equipment on the cart. Mack needed to run a couple of power cords/cables through the front of the cart, instead of

the back, based on the location of the camera table. Otherwise, the set-up was efficient and reduced set-up time dramatically. Once staff becomes a little more familiar with the location of cables/cords this process will improve even more.

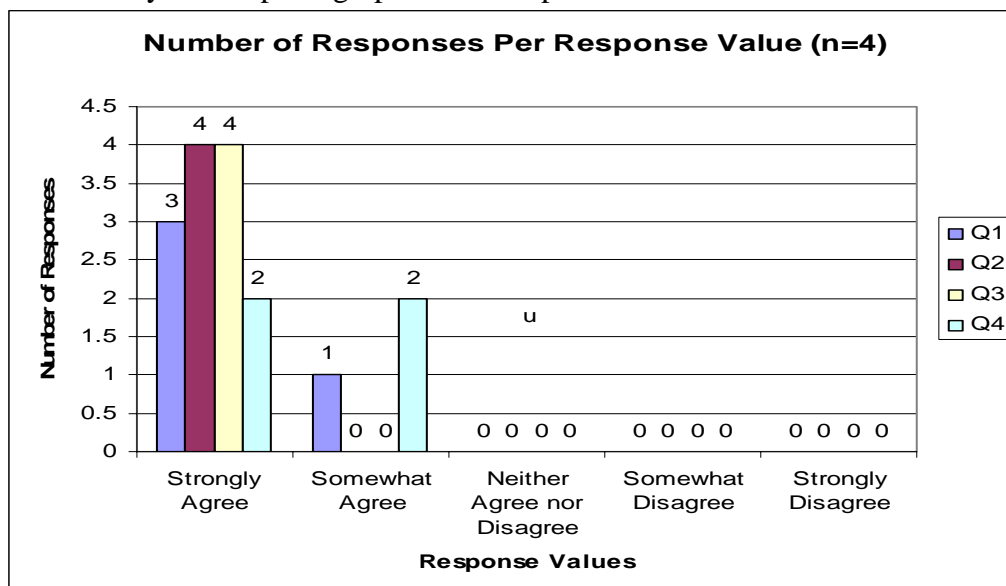
3. **Personnel Shortage** – It is my recommendation that no less than two people should be present at all community events.
4. **Wireless connection** – Staff does not know how to establish a wireless connection from the registration computer to the server. For this event, the cable ran across the hallway into the other exam room. Fortunately, the exam rooms were at the end of the hallway. Staff should be trained and instructions need to be added to the camera assembly manual for wireless operations.

Note: Silowash investigated trying to resolve the wireless network issue. Since we are collecting personal information a wireless network system is strongly discouraged. Unless there is very sophisticated encryption program the risk would be run of having our information available to anyone who really wanted it.

Survey Results:

Four of ten people (40%) completed screening surveys. Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on the graph.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concerned for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.



Evaluation Report

Fairchance Health Clinic

August 3, 2006

Site Description:

This event occurred in Fairchance, Pennsylvania. It was a small clinic that served the local community. It was from 10:00 to 2:00.

Attending Personnel:

Barb Mack
Russell Silowash

Summary:

Silowash arrived at 9:20 am. The location was somewhat difficult to find because of the unfamiliarity of the area and the size of the site. The retinal screening van arrived at the site at 9:00 am. Unlike other sites, this site was relatively small and was more of a clinical setting than a community setting; people who had diabetes and were interested in our study were told to come see us by the site's coordinator. The camera, computer, and LAN set-up went very smoothly and with no complications. However, registration of the participants had to occur in the same room as imaging because of the lack of space. The camera and computer were set up in a very small exam room, and the room had a window in it. The window provided too much light for the camera to work properly; shadows were present on many of the images. One participant could not get imaged because they had a very small pupil size, and the room was not dark enough. After many attempts to darken the room with white blankets, Silowash retrieved a thick, dark colored blanket from his car. Once placed over the window, the room was dark enough to obtain better images, and minimal shadows were encountered.

Retinal screenings commenced at 10:00 am. Once the screening of participants started, Mack would carefully go over the consent form with them. Approximately three people were turned down from the study due to not having diabetes. Once the window problem was solved, imaging went very smoothly, and approximately nine people were screened. Retinal screenings ended around 2:30 pm. It took approximately thirty minutes to break down the equipment and put it in the van.

Needs:

1. **Black Cart** - The black cart purchased for this program was supposed to be used as a storage center for a working hub; the person in charge of set-up would only have to plug the cart in, and the system would work properly. This was not the case. The cart was only used as a storage space for all of the computer equipment. Even though this made unloading and loading the van much easier and efficient, the cart would really be beneficial and more efficient if it was used as it should be.

Solution: Steve Uttecht and Russell Silowash plan to finish building all of the carts on August 4, 2006. The cart in the van now has a keyboard drawer, adjustable monitor arm, and a shelf. These components enabled the computer and LAN system to be assembled within the cart and tested. The cart should be fully functional for the next community outing. By setting up the cart appropriately, set-up time and problems will be reduced.

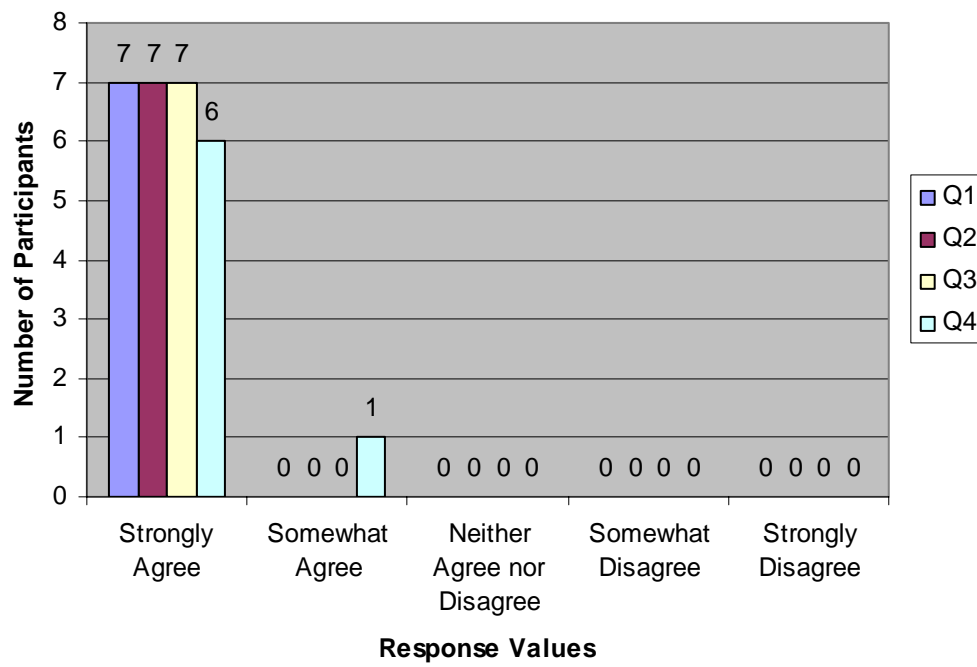
2. **Office Supplies** - Office supplies could make the teleophthalmology project more organized and prepared for any type of situation. For instance, plastic mail bins could be used to organize the unsigned consent forms from signed consent forms. Materials could be bought that would allow the retinal screening team to adapt to different lighting situations. The site coordinator at Fairchance stated that many of the sites in Fayette County would not have optimum lighting conditions, so we should be better prepared for the next upcoming events.
3. **Personnel Shortage** - Two people were at this site. However, an evaluation team member may not be present at all times to help set-up and break down of the retinal screening equipment. This could create future problems, because the equipment is rather heavy, especially the camera. One person assigned to this project should be able to easily lift approximately one hundred pounds. This situation could become problematic. There has been some talk of getting people from the sites that are strong enough to lift the camera. However, this could have legal implications, if the person should hurt themselves while lifting the camera as well as damage the camera.
4. **Rewards** - The teleophthalmology group did not have any key chains to give away this event. More key chains should be ordered in order to give participants more incentive to have their images done.

Survey Results:

Seven people completed the survey out of nine total people (77.8%). Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on the graph.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concerned for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.

Number of Participants Per Response (n=7)



Evaluation Report

Carmichaels Site

August 23, 2006

Site Description:

This community setting took place at the Carmichaels Volunteer Fire Department Center in Greene County Pennsylvania during the annual Bituminous Coal Festival. The event lasted from 6:00 pm until approximately 9:15 pm, and had a health fair setting. Because of the amount of space available, Silowash was able to assemble the IMITS poster and have additional information available concerning the IMITS program.

Personnel Attending:

Barb Mack
Faith Bivins
Russell Silowash

Summary:

Silowash arrived at the site at 5:25 pm. Upon arrival, the retinal screening equipment had been assembled, and Mack had already taken a test shot. Silowash assembled the IMITS poster and placed the IMITS information as well as the Diabetes Retinopathy Screening posters on the table. The first participant was registered at approximately 5:45 pm. The camera system was assembled in a newly-renovated bathroom of the facility, while the registration equipment was located at a table just outside of the bathroom. The bathroom was capable of complete darkness, so light was not a factor in image quality. Mack reported that the camera and LAN were assembled and tested in no more than twenty minutes. Bivins registered participants while Mack imaged participants and Silowash consented participants. If Bivins came across a problem during registration, either Mack or Silowash helped to solve the problem. Mack was very alert to all of Bivins actions and corrected Bivins if any mistakes were being made. Bivins accidentally started registering participants before properly consenting them a few times. Mack noticed this problem and corrected it; all registered participants were properly consented before imaged.

The event was well attended by the Carmichael's population. The retinal screening team was able to image 18 people successfully. Unlike the last event, there were no equipment problems. Fourteen people completed surveys.

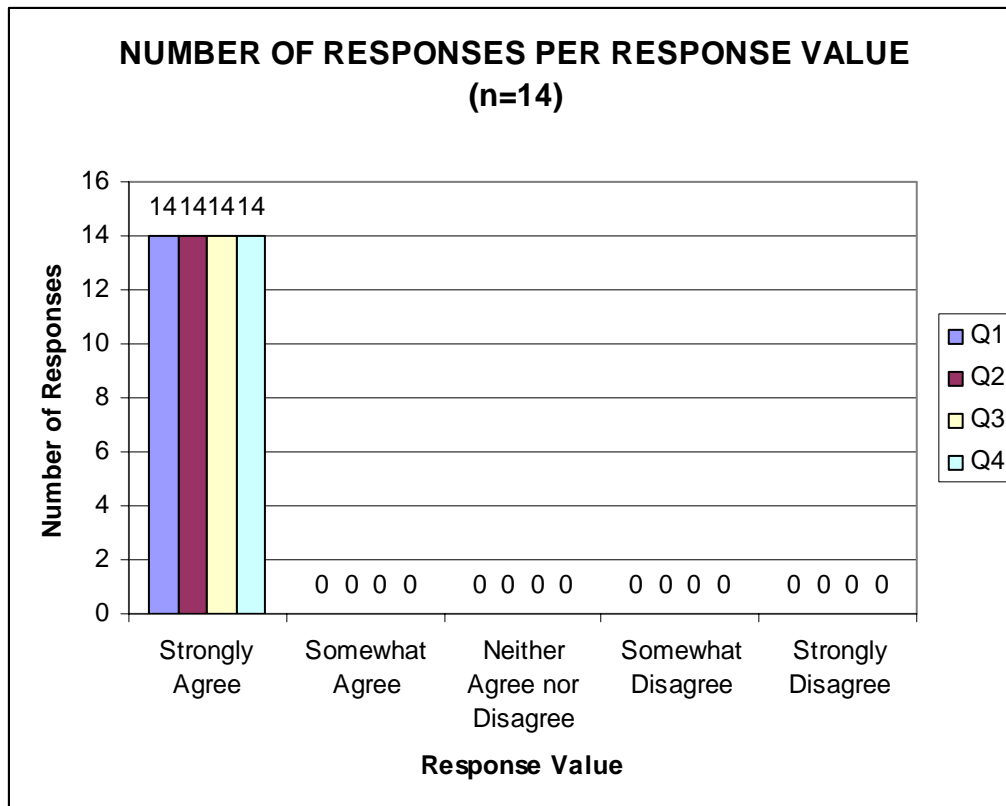
Problems:

- 1. Office Supplies** – Silowash purchased zip ties to organize all of the wires associated with the set-up. He also brought duct tape to tape down any wires that may trip participants and/or staff. Thumb tacks were also purchased to hang blankets over windows. Mack reported that her business cards are going to be completed soon, and Leslie Anthony has ordered file organizers for consent forms and easels for posters.
- 2. Equipment** – Both Bivins and Silowash have reported that the mouse has been problematic when registering participants. The six button mouse erases information if the wrong button is accidentally pressed. This problem may be solved by implementing a two button mouse. It might be possible to either purchase or trade for a two button mouse for the upcoming events.

Survey Results:

Fourteen participants out of a possible eighteen (77.8%) completed surveys. Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on the graph.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concerned for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.



We now have a total of 80 completed surveys.

Key Quotes:

1. "Everyone was very nice and completely helpful. Thank you."
2. "Everything went smoothly."

Evaluation Report

Uniontown Hospital Diabetes Clinic

August 22, 2006

Site Description:

This retinal screening took place at Uniontown Hospital's Diabetes Clinic. It was the grand opening for the newly established diabetes clinic and Congressman Murtha was present to dedicate the clinic. The new diabetes clinic at Uniontown Hospital is part of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) program.

Attending Personnel:

Barb Mack
Faith Bivins
Robb Wilson
Russell Silowash

Summary:

The evaluation team arrived at 9:20 am; the retinal screening team had arrived before hand and had already unloaded the equipment. The camera system was located in a medium sized exam room, while the registration equipment was located in another exam room. The participants were consented in an office adjacent to the exam rooms or in the registration room. Set-up of the equipment took approximately twenty minutes. Congressman Murtha arrived at 9:40 am, which was 20 minutes earlier than his scheduled time. Because of this, the retinal screening team was unable to demonstrate the camera for Mr. Murtha; however, the team was able to show him example images. Wilson approached Mr. Murtha about the study and spoke with him about the IMITS program in general. Mr. Murtha seemed very interested in the retinal screening project as well as the IMITS program. Mr. Murtha thought that the van was the location for the retinal screening, and appeared confused when he had to go into the clinic to see the camera system. At 10:00 am, Congressman Murtha went outside the clinic to give a speech and to talk about the importance of diabetic treatment in Fayette County.

Once Congressman Murtha's speech and dedication of the newly established clinic was over, the retinal screening team started screening diabetic participants. The main influx of participants did not occur until after 1:00 pm. Announcements were made over the public announcement system of the hospital regarding the project, and handouts were given at the information desk of the hospital. The evaluation team obtained completed surveys from the participants. For this site, the retinal screening team was able to screen 10 participants successfully. However, during the imaging of the sixth participant, the team ran into apparent software problems and was unable to finish imaging of the sixth participant. After restarting the imaging software as well as the computer, the problem persisted, and Steve Uttecht was contacted immediately. Steve helped the team find the

problem, which was a wire connection problem, and the screening process was enabled once again. The problem was fixed in approximately 15 minutes.

Bivins was a newly added member to the retinal screening team. Mack and Bivins were able to successfully lift the camera from its case during set-up. Bivins was also being trained on imaging and registration of the participants. Also, Mack was asked how she felt about the new cart that was assembled for the project. She felt that it was very helpful, and it definitely decreased set-up time. The only complaint she had was the need for zip ties to straighten up the wires associated with the system. The diabetic retinopathy team was able to successfully load and unload the equipment onto the van. The addition of one extra person to the team is definitely helpful and needed.

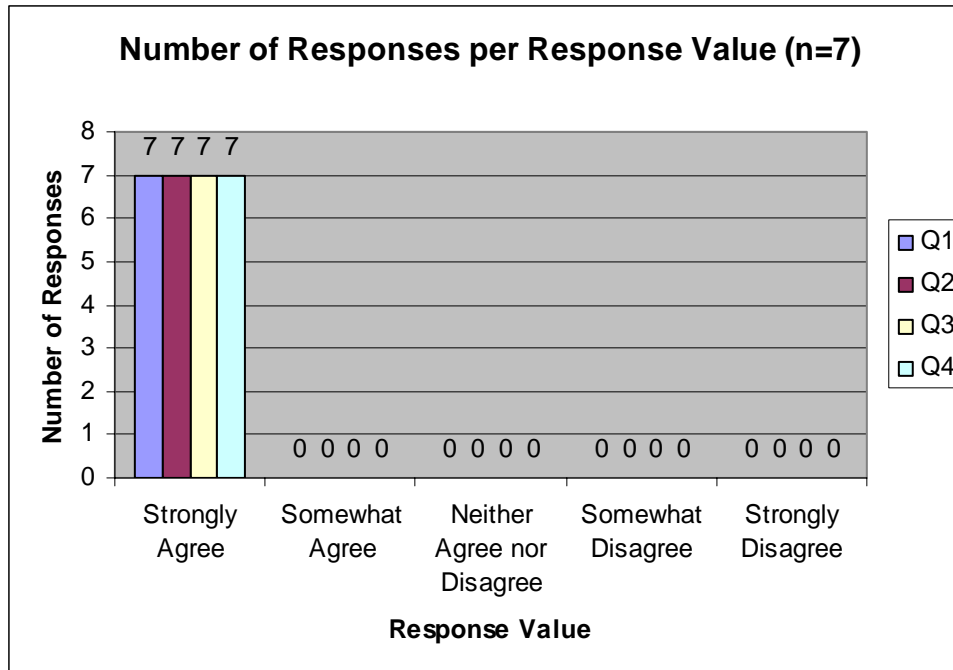
Needs:

1. **Office supplies** - The diabetic retinopathy program still needs to purchase a variety of office supplies. These supplies include but are not limited to: duct tape, push pins, mail bins, zip ties, and business cards for team members.
 - **Solution:** Silowash has volunteered to purchase zip ties, push pins, and duct tape for the project. Leslie Anthony has ordered easels for the posters as well as a file box for the variety of forms involved in the program. Mack reported that her business cards were still being completed.
2. **Van flexibility** - Mack mentioned that the van should be able to function as the screening room. Silowash mentioned that the van would need to have air conditioning capable of cooling the entire van efficiently for both team members and participants. If the van was capable of being the screening room, the project would be completely mobile and could be flexible with any community setting.

Survey Results:

Seven out of ten participants completed screening surveys (70%). Here are the questions from the survey and will be represented graphically below.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concern for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.



Key Quotes:

1. “The staff was kind and considerate.”
2. “Their explanations were clear and concise.”
3. “Thank you for this opportunity.”
4. “Very exciting!”

Evaluation Report

Indiana Regional Medical Center

August 25, 2006

Site Description:

This retinal screening took place at the Indiana Regional Medical Center. Congressman Murtha was present to speak on the importance of diabetes care. The diabetes clinic at the Indiana Regional Medical Center is part of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) program.

Attending Personnel:

Barb Mack
Faith Bivins
Robb Wilson
Russell Silowash

Summary:

The event was billed as Diabetes Day. Three large areas of the medical center were devoted to the health fair. None of these areas provided any secluded dark sections. Two other types of vision tests had booths. Retinal screening was not scheduled to be done that day. After explaining the needs to the clinical staff, an office was vacated where both the camera and registration equipment could be set-up. Unfortunately it was a good deal away from the actual health fair. Silowash and Wilson escorted participants to and from the office where Bivins and Mack consented, registered, and imaged.

The health fair was well attended. Congressman Murtha spoke as well as members of the University of Pittsburgh Diabetes Institute. Numerous attendees waited to have their eyes imaged. However, during imaging the team ran into problems. Parts of the equipment shut down and would not allow completion of a participant. This was not a problem seen before and Steve Uttecht was contacted immediately. After some time the equipment was adjusted and began to work again. Five participants were lost due to wait time. The remainder of the day proceeded normally.

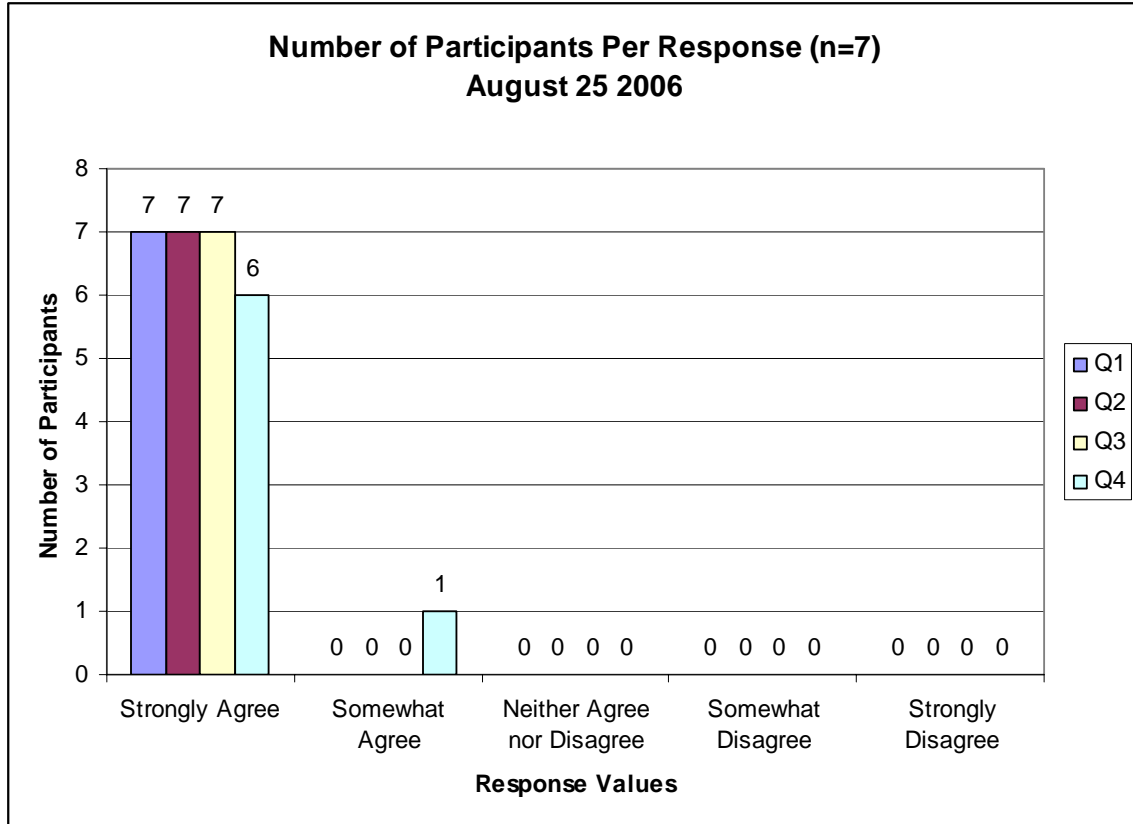
Needs:

Improve communication to assure that those in charge of the clinic or health fair are aware of the special needs of the retinal imaging equipment. Also communication among team members needs to be better.

Survey Results:

Seven people completed the survey. Here are the questions from the survey and will be represented graphically below.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concern for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.



Evaluation Report
Lincoln-Lemington Family Health Care Clinic
November 2, 2006

Site Description:

This retinal screening took place in a clinic in lower income portion of the city of Pittsburgh. The patient population was older and minority based. Participants were scheduled to report at designated times. Participants were scheduled from 12:30 pm to 4:30 pm.

Attending Personnel:

Barb Mack
Robb Wilson

Summary:

Registration and camera were set up in the same room. The room was not being used for any other purposes that day and it was able to have complete darkness. The room was removed somewhat from the clinic area near the kitchen and conference room. Participants were escorted back to the room by clinical personnel and seemed not to have any problems. Mack reported that she asked a clinic staff person to help her unload the camera. She also reported that she had no problems with the functionality of the equipment. Six participants were imaged.

Needs:

Not every participant that was scheduled to be imaged kept their appointment. There was too much down time for imager. A solution could be to work more with the clinical staff to send some sort of reminders to the participants.

**Teleophthalmology
Evaluation Team
Retinal Screening Program
Survey 2006**

**Integrated Medical Information Technology System
Teleophthalmology Retinal Screening Program Survey**

Thank you for your participation in the Retinopathy Screening Program. Below are a few questions that we would like you to answer about the screening process. Please circle the ONE best answer.

Date: ____ / ____ / **2006**

1. The Health Professionals took time to talk with me about the screening process.

Strongly Agree 1	Somewhat Agree 2	Neither Agree nor Disagree 3	Somewhat Disagree 4	Strongly Disagree 5
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2. The Health Professionals were friendly and showed concern for me.

Strongly Agree 1	Somewhat Agree 2	Neither Agree nor Disagree 3	Somewhat Disagree 4	Strongly Disagree 5
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3. I was comfortable with the way the equipment and camera were used.

Strongly Agree 1	Somewhat Agree 2	Neither Agree nor Disagree 3	Somewhat Disagree 4	Strongly Disagree 5
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4. The wait time for my retinal photographs was acceptable.

Strongly Agree 1	Somewhat Agree 2	Neither Agree nor Disagree 3	Somewhat Disagree 4	Strongly Disagree 5
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5. Please list suggestions for improvements:

-
-
-

Place your completed survey in the attached envelope, seal it and give it to a Health Professional.

All personal identifiers will be removed from this survey before it is delivered to the research staff.

The Integrated Medical Information Technology System (IMITS) Program was made possible by a grant initiative between the University of Pittsburgh Medical Center and the Department of Defense. Phone: 412.647-7187

**Teleophthalmology
Evaluation Team
Clinical Breakfast Meetings
2006**

**General Internal Medicine
Diabetes and Endocrinology Clinic**

Teleophthalmology
Clinical Breakfast Meeting
General Internal Medicine (GIM) MUH
February 3, 2006

Eleven to twelve MAs and/or nurses arrived for breakfast at 8AM. Some came and went while waiting for Dr Eller to arrive. Some came late after talk was over but imagers remained to talk with staff.

It seems all the staff now knows Larry Jefferson. The group may need more information on diabetic retinopathy – Dr Eller proposed coming back with a talk. This was well received.

Staff had questions concerning the posters/flyers. It was explained that a request was submitted to both the Pitt and AF IRB to request permission to produce posters/flyers. It was also explained that a question will be added to the GIM check-in tablets which will ask the patient if they would be interested in retinal screening. Some were confused that they couldn't order a retinal screening without first checking with MD. It was explained how this was a study and not something that needs to be ordered by MD. We also explained the need for the consent forms and how the patient will be followed by the Diabetes Institute.

Staff volunteered to have their own images taken so that they could experience what they would be suggesting to the patient. Also taking the staff to the imaging room now let them know where the room was located.

Teleophthalmology
Clinical Breakfast Meeting
Diabetes and Endocrinology Clinic, 2nd floor Falk Clinic
March 3, 2006

Ten to twelve MAs and/or nurses arrived for breakfast at 9AM. Some came and went while waiting for Dr Eller to arrive.

The staff requested that clinic MD be identified on the patient's form. This could be put in the comment section.

There will be consent forms outside of exam rooms (12 rooms) so that the staff could give one to patient while they wait for the MD.

Monica Cassimir and Larry Jefferson worked with staff to provide them the experience of being imaged.

Currently Monica has a problem with patients not waiting. It is easy for the patient after leaving the office to exit the building bypassing the retinal imaging area. The office is too far removed from the exit. Staff suggested that Monica walk through the hallways to help recruit, but because space is limited this would not be easy to do. A better suggestion was that staff would phone Monica and have her come to the exam room to escort patient to image room.

Monica asked if the patient's chart could be identified if they would qualify perhaps mark it with a brightly colored post-it note.

Monica also felt that she was loosing patients over the length of the consent form – Barb Mack will work with both Larry and Monica on better paraphrasing.

Again the staff asked for posters/flyers to advertise the study. Posters and flyers that have been approved by Pitt IRB but now must go thru the AF. Only two changes were made from the IRB one to remove the word *free* and the other to change *simple* to *easy*.

On question that remained was what prevents patients from returning and having a second image done? It was not determined if this would be flagged in clinic or later in the data set.

Another question which the clinic manager can help with was can we find out the number of patients with diabetes that came to clinic?

Teleophthalmology Evaluation Team Clinical Focus Group Reports 2006

**Diabetes and Endocrinology Clinic
General Internal Medicine**

Diabetes and Endocrinology Clinic Focus Group
9/1/2006

Clinical Staff

- cannot remember to ask patient
- often in hurry
- willing to help with study

Imager

- no problems with Monica

Patients

- often in hurry
- may have recently had eye exam
- possibly offer patient small incentive e.g. free parking
- needs referral from MD

Physicians

- needs to refer patient
- physicians not aware enough or informed to recommend to patient
- physician will have to write order if linked to Epicare
- physicians need more information.

Medical History

- include question on both Medical History Update and New Patient History forms
- need to ask Janice Zgibor if we need further IRB approval
- Joanne Spino needs to ask for permission to include on form.

Consent Forms

- supply to clinic staff
- have consent forms ready to give to patient to read while waiting
- patient would have a chance to ask physician about study
- clinic staff person reading patient forms could give patient consent form

Signage

- print more flyers
- use colored paper
- supply waiting room – put on tables
- attach to back of Medical History Update and New Patient History forms
- increase size of flyer to poster size
- post in all twelve exam rooms plus waiting area

General Internal Medicine Focus Group
9/8/2006

Clinical Staff

- depend on physician to write order
- operates 8:00 AM – 6:00 PM
- do supply physician orders to patients
- willing to help
- willing to give patient copy of flyer
- experienced times when pager not answered
- have given patient phone number to call
- cannot use text pager

Imager

- Faith needs to be introduced to clinical staff, she will contact Cece Stafford to arrange
- Faith needs to supply clinical staff with correct pager number, instructions for paging and include flyers for 8 pods
- supply clinical staff with hours available
- GIM will not supply space for Faith

Patients

- often in hurry
- not always willing to wait for imager to be paged
- physician order needed for retinal screening

Physicians

- need more information
- need to see value of retinal screening
- train new physicians that started in July – include retinal screening in orientation materials
- supply order needed for retinal screening

Medical History

- include retinal screening question in tablets given to the patient
- no provision if patient gets hard copy to complete

Consent Forms

- clinical staff do not have consent forms
- staff does not have time to give to patients
- clinical staff does not have knowledge if asked questions concerning consent form

Signage

- print more flyers
- use colored paper

- increase size of flyer to poster size for exam rooms, waiting areas and classrooms
- supply for 8 pods, 4 checkout areas and 2 at front desk.

System Status

- received email that system was down – never received information that system running again
- must receive notice
- stopped sending patients for months

Diabetes Education Class

- sometimes patients are seen after physician's visit
- sometimes patients just come in for a visit with the diabetes educator
- need to include diabetes educators
- new classes starting September/October
- diabetes educators can write orders.